AMO ADVANCED MEDICAL OPTICS	DOCUMENT NO: Z370049 REVISION: 08
LABEL SPECIFICATION	
TITLE: SOVEREIGN™ COMPACT OWNER'S MANUAL (US)	

SPECIFICATION:

1. **BINDER:**
   1-1/2" white vinyl with clear-view and insert pockets or equivalent. Three rings.

2. **TEXT:**
   Paper stock: 24 lb. White laser paper, 8-1/2" x 11", 3 ring punched.
   Print: one color-black printing on one side. Printing to be clear, and legible with no ink smears. Each chapter must start on a right-facing page.

3. **COVER & SPINE:**
   See Z330059 for Label Specifications

4. **TABS PAGES:**
   See Z330058 for Label Specifications.

5. **ASSEMBLY ORGANIZAITON:**
   Index tabs in appropriate sections of Manual.

6. **PACKAGING:**
   Shrink-wrap assembled binder with copy of first page of document (cover page) between shrink and outside of binder. Manual identify from cover page (version, part number, etc.) must be facing out and visible for warehouse identification.

7. **Point of Use:** AMO, Santa Clara
   Sanmina-SCI Corp.

SUMMARY OF CHANGES

APPROVAL DATE	DCN/LCR NUMBER	VER.	DESCRIPTION OF CHANGE
5/13/05	20050506	5.0	Update Manual for the Open-Toe-Footpedal
7/27/05	LCR20050746	6.0	Added disposal procedures for waste electronic equipment and updated trademarks.
10/24/05	LCR20051275	7.0	Added open toe foot pedal SKU # & new accessory for the Sovereign Compact System.

REVISION	DESCRIPTION OF CHANGE
08	Add China RoHS symbols/definitions on page 8-9. Add Chines/English tables at the end of section 8. Add Point of Use on the Label Spec.

SOVEREIGN™ COMPACT

OWNER'S AND OPERATOR'S MANUAL

Manufactured for:
Advanced Medical Optics, Inc.
1700 East St. Andrew Place
Santa Ana, CA 92705
U.S.A.

www.amo-inc.com

CE
0050

AMO Ireland
Dublin 4
Ireland

For Order Placement of Surgical Products

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Call 1-800-366-6554

For Phaco Returns or Technical Service

Call 1-800-449-3060

All returns must be accompanied by a RGA#

(Returned Goods Authorization)

Manual Replacement
Order# CMPZ370049

3032972

PHACOEMULSIFICATION SYSTEM
WITH RESPECT TO ELECTRIC SHOCK, FIRE
AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL2601-1/CAN/CSA C22.2 NO. 601.1
50KK

AMO™
ADVANCED MEDICAL OPTICS

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SOLO is a trademark of Microsurgical Technology.

Rx Only Z370049 Rev. 08 0407
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This manual is written to familiarize all surgical team members who will set-up and operate the SOVEREIGN™ COMPACT System with the components, set-up, operation and care of your system and its accessories. **You should read and understand this manual completely before using the SOVEREIGN™ COMPACT System in surgery.**

SOVEREIGN™ COMPACT System is produced under at least one of the following U.S. Letters Patent Nos.: D426,882; D462,759; D463,380; D463,545; 4,983,901; 5,230,614; 5,268,624; 5,342,293; 5,392,653; 5,470,312; 5,591,127; 5,649,905; 5,700,240; 5,852,794; 6,033,376; 6,059,765; 6,083,193; 6,260,434; 6,261,297; 6,360,630; 6,361,520; 6,394,974; 6,398,754; 6,423,074; 6,452,120; 6,452,123; 6,520,929; 6,533,750; 6,579,255; 6,585,683; 6,605,054; 6,629,948; 6,674,030; 6,699,212; 6,780,165; and 6,852,092. Also, European patent Nos.: 0,643,570; 0,643,808; 0,643,823; 0,664,898; 0,705,084; 0,741,554; 0,954,386; 1,012,686; and 1,056,420. Patents pending. Other foreign equivalents available upon request.

WHITESTAR™ System is produced under at least one of the following U.S. Letters Patent Nos.: 6,629,948 and 6,780,165. Patents pending. Foreign equivalents available upon request.

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1 INTRODUCTION

In this section you will find:

- About Phacoemulsification
- About This Manual
- Declaration of Conformity
- Intended Use
- SOVEREIGN™ COMPACT System Features
- SOVEREIGN™ COMPACT Operating Modes

About Phacoemulsification

Over thirty years ago, Dr. Charles Kelman conceived and developed phacoemulsification, a method of cataract removal by ultrasonic emulsification and aspiration of the cataractous lens through a small incision. Phacoemulsification is advantageous for both patient and surgeon:

- greater intraoperative control.
- the smaller incision requires fewer or no sutures, poses less risk of infection and induced astigmatism, and gives better long and short term predictability of vision.
- patients are able to resume normal activity much sooner and with fewer restrictions than with traditional cataract extraction surgeries.

Advanced Medical Optics, Inc. (AMO) supports phacoemulsification with sophisticated instrumentation that optimizes the benefits of this surgical procedure.

About This Manual

This manual includes information regarding optional SOVEREIGN™ COMPACT System enhancements. The availability of these features in your SOVEREIGN™ COMPACT System configuration and availability in your area may be confirmed by your AMO representative.

DECLARATION OF CONFORMITY

Application of Council Directive.....Medical Devices Directive 93/42/EEC

Standards to which Conformity is Declared .....IEC 601-1
EN 60601-1-2
EN 60601-2-2

Supplier.....Advanced Medical Optics, Inc.

Address .....Santa Ana, CA 92705
U.S.A.

Product .....SOVEREIGN™ COMPACT

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive.

Place: Santa Ana, California

Signature: Sandra Selvaggi

Date: October 23, 2007

Full Name: Sandra Selvaggi

Position: Vice President
Quality Assurance
Advanced Medical Optics, Inc.

CE
0050

Intended Use

The SOVEREIGN™ COMPACT Cataract Extraction System is an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

This HIGH FREQUENCY (HF) SURGICAL EQUIPMENT is specified for use without a NEUTRAL ELECTRODE.

SOVEREIGN™ COMPACT System Features

The SOVEREIGN™ COMPACT System represents over 7 generations of AMO™ phacoemulsification technology. Safety, ease-of-use, and reliability are designed and manufactured into every SOVEREIGN™ COMPACT System. SOVEREIGN™ COMPACT System meets UL (Underwriter's Laboratory), I.E.C. (International Electrotechnical Commission) 601-1 and E.M.C.(Electromagnetic Compatibility) requirements for this type of device.

The SOVEREIGN™ COMPACT System contains a number of features based on extensive research and clinical trials with highly-trained and noted ophthalmologists who are experienced phacoemulsification surgeons.

WHITESTAR™ Technology

Optional WHITESTAR™ Technology enhancement for the SOVEREIGN™ COMPACT System delivers finely modulated pulses of energy, interrupted by extremely brief cooling periods. This allows the SOVEREIGN™ COMPACT System to achieve full ultrasound cutting efficiency and magnetic followability, while introducing less energy int the eye.

Advanced Fluidics System

One of the most advanced features of the SOVEREIGN™ COMPACT System is its fluidics system that allows for intraoperative intraocular control. An integral part of the advanced fluidics is resident in the patented technology of the disposable and reusable tubing packs. The fluidics system is fully closed and isolated providing the maximum safety and minimum biohazard risk.

Phacoemulsification Ultrasonic Handpiece

The Phacoemulsification Ultrasonic Handpiece has been designed with a straight-through aspiration channel for more efficient removal of nuclear fragments, to minimize clogging and to facilitate easy cleaning. The hand piece is lightweight, slim, and well-balanced, making it comfortable to use and easy to manipulate.

Foot Pedal

The operating modes (Diathermy, I/A, Phaco and Vitrectomy) are controlled by the foot pedal. The degree of travel for each foot pedal position may be selected and saved in memory for each surgeon/procedure.

Reflux is activated by a programmable switch, giving immediate response. The two lateral foot pedal side switches may also be programmed to change between surgical sub-modes. Surgeon control of continuous irrigation is also available through the foot pedal. The foot pedal housing is waterproof to comply with I.E.C. 601 requirements.

SOVEREIGN™ COMPACT Display

The SOVEREIGN™ COMPACT System screen display is easy to read and easy to operate. You will know at a glance the exact status of the machine. The LCD display gives you visual indication of modes, settings, and system status. Messages cue you through the procedure, and error messages indicate improper connections or selections. All instrument connections are easily accessed from the front for easy setup and less obstruction of the front panel displays.

Multi-Lingual User Interface

The User Interface is available in 14 languages, easily selected from the opening display screens. Once selected, all of the programming and operating screens are in the selected language, and the chosen language remains in effect until otherwise changed.

SOVEREIGN™ COMPACT System Cart	Operating Room teams contributed significantly to the successful design of the SOVEREIGN™ COMPACT System Cart. Its solid wheel base and two locking wheels make it stable and smooth rolling. An open design minimizes weight. A manually adjustable height Mayo tray with baling ring accommodates either an autoclavable instrument tray or a solid tray. A tray for the remote control provides easy access under the sterile drape. An open bin and footpedal platform are available for storage.
Programmable Power Pole	The automated and programmable power pole allows adjustment of the bottle height through each procedural phase. Two adjustment keys on the front control panel or the remote control are used to accurately raise and lower the bottled saline solution, while maintaining the sterility of the operating field. A separate circulator up/down switch allows access at the rear of the system. The pole is easily removed from the cart for transport.
Remote Control	The SOVEREIGN™ COMPACT System can be operated/controlled from the remote control keypad. All modes can be remotely accessed, and all parameters may be adjusted using the remote control, including full programming and prime capabilities. Backlighting supports low light OR conditions.
Prime/Tune	The system incorporates a variety of prime and tune options for various purposes. The comprehensive Prime & Tune mode includes tubing purge and fill, phaco handpiece tune and vacuum check. Other choices are I/A Prime and Phaco Tune only, tune only, and irrigation free flow. Irrigation free flow can be used to set up the case without use of the footpedal. Collecting irrigation may occur prior to priming.
Continuous Irrigation	Continuous Irrigation is immediately available via dedicated keys on both the front panel and remote control. Surgeon control via footpedal programming is also available.
Programmable Operating Parameters	The SOVEREIGN™ COMPACT System is programmable through the color screen displays and front panel keypad. The surgeon may preselect his/her desired settings for each portion of the surgical procedure. Up to 16 different setups, or "surgeon names," plus the AMO default settings program may be stored in the instrument program memory. This allows different users to preset their preferences, or an individual user to preselect setups for different procedures.
MMP	Multiple sub-mode memories are available within SOVEREIGN™ COMPACT (Multiple Modulation Presets) operating modes. This allows users to preset their parameters for specific techniques such as phaco chop or viscoelastic removal.

SOVEREIGN™ COMPACT Operating Modes

The SOVEREIGN™ COMPACT System has been designed to provide all the surgical capabilities desired by the anterior segment/cataract surgeon. These capabilities include:

Bipolar Diathermy (DIA)

This mode is used by most surgeons to coagulate blood vessels during the procedure and by some surgeons to "coapt" the conjunctiva at the end of the procedure. An isolated output frequency allows non-contact tissue coagulation, eliminating adhesion and traction. Also, the depth of penetration of the energy field is less than that of higher frequency units, minimizing tissue shrinkage or charring. The gentleness of the diathermy mode allows the surgeon to stop "bleeders" within the incision with only minimal scleral shrinkage, and to stop a "bleeder" from a 10-0 suture tract without melting the suture.

Phacoemulsification (PHACO)

This mode is used to break up (emulsify) the nucleus of the lens, allowing it to be aspirated from the eye through a small incision. The continuous autotuning circuitry maximizes the emulsification efficiency for each lens density, even varying densities within the same lens. Phaco time is displayed in minutes and seconds. Convenient selection of linear or panel-preset phaco power, in a variety of power delivery options (pulsed, burst etc.), gives the surgeon increased precision and control.

Irrigation/Aspiration (I/A)

This mode allows for controlled aspiration of cortical material from the eye, while maintaining intraocular stability by replacing the aspirated material with irrigation solution. A peristaltic pump provides a predictable and stable aspiration rate. Complete control is achieved with "ASPIRATION RATE" and "VACUUM". Irrigation is gravity-fed and is mode regulated by adjusting the height of the irrigating solution bottle. This mode gives you flexible control of each case with independently adjustable vacuum level and flow rate settings. The adjustable volume tone indicates the vacuum level.

Anterior Vitrectomy (VIT)

This mode is used to remove vitreous from the anterior chamber of the eye during a secondary IOL (intraocular lens) implant procedure, or following vitreous loss associated with trauma, or vitreous loss during primary cataract surgery. If vitreous is lost during cataract surgery, the vitrectomy capability can be ready and available in seconds.

Programmable Power Pole Capability

The SOVEREIGN™ COMPACT System is equipped with a programmable power pole. If the programmable power pole capability is activated at the beginning of the customizing program sequence, programmable power pole height settings can be entered independently for each of the Phaco MMP modes plus settings for Diathermy, I/A and Vitrectomy. During surgery, the programmable power pole height will change to the preprogrammed height when switching modes.

Occlusion Mode Phaco

Occlusion Mode Phaco is used to regulate the vacuum rise time that is experienced following occlusion of the phaco tip, without limiting the choice of aspiration rate through an unoccluded needle. In order to independently control aspiration rate and vacuum rise time, it is possible to have a different aspiration rate when the needle is occluded than when the needle is not occluded.

Occlusion Mode Phaco is also used to regulate ultrasound power modulation. The power modulation of the phaco handpiece (continuous, pulse, burst) can be programmed to automatically change when the phaco tip changes from an unoccluded condition to an occluded condition.

2 SYSTEM COMPONENTS

In this section you will find:

- Receipt and Inspection Instructions
- SOVEREIGN™ COMPACT System Components
- SOVEREIGN™ COMPACT System Pack

Receipt and Inspection

When you receive your SOVEREIGN™ COMPACT System inspect the exterior packaging for any signs of damage that may have occurred during shipping and record this damage on the shipping documents. **If there are any signs of damage,** carefully unpack the SOVEREIGN™ COMPACT System and inspect it for damage. If any damage to the package contents has occurred, you must immediately file a claim with the transporter. Transporters will accept claims only from the recipient (you), not the shipper (AMO).

Your AMO Representative will have contacted you to schedule both Installation and In-Service Training upon receipt of your new SOVEREIGN™ COMPACT System. **We suggest that you leave the SOVEREIGN™ COMPACT System in its original packaging and store it in a cool, dry environment** until AMO installation personnel arrive to assemble, install and test your equipment. Extreme heat, cold or moisture can damage any electronic equipment.

SOVEREIGN™ COMPACT System Components

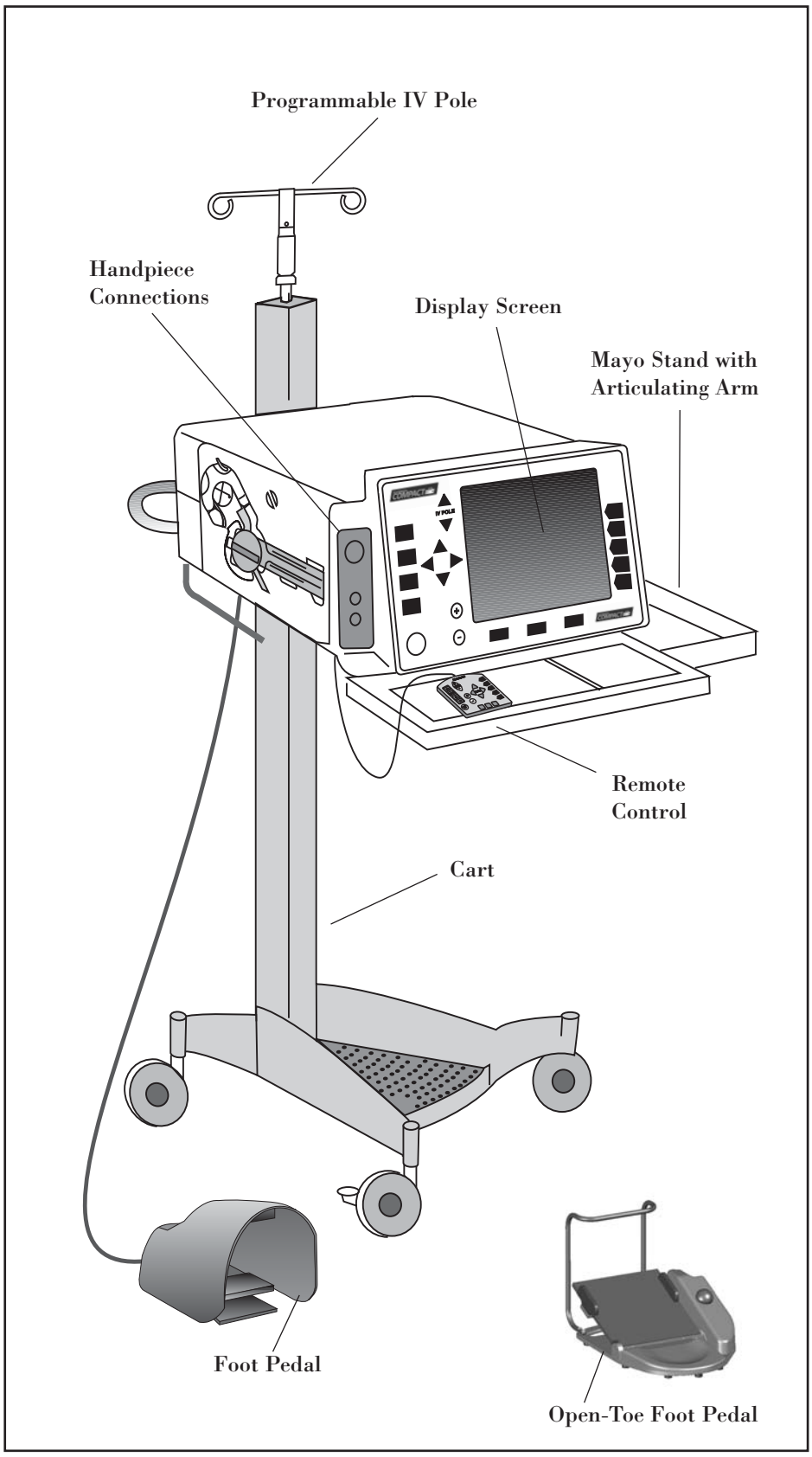
Your SOVEREIGN™ COMPACT System may consist of some or all of the following components:

- SOVEREIGN™ COMPACT System Console
- Programmable IV Pole
- Cart with Mayo Stand
- Instrument Sterilization Tray (s)
- Phacoemulsification Ultrasonic Handpiece
- OPO60 Disposable Tubing Pack or OPO65 Reusable Tubing Pack
- Diathermy Cord with Bipolar Forceps
- Electronic Oscillating Vitrectomy Handpiece
- Foot Pedal with Cord
- Power Cord (detachable)
- Remote Control Module with Cord
- SOVEREIGN™ COMPACT System Owner's Manual
- SOLO™ I/A Handpiece, 20 Gauge, Curved Silicone Sleeve Tip
- SOLO™ I/A Handpiece, 20 Gauge, 45˚ Silicone Sleeve Tip
- SOLO™ I/A Handpiece, 20 Gauge, Straight Silicone Sleeve Tip
- Spike Mat

The major system components are identified in Figure 2.1.

Figure 2.1

SOVEREIGN™ COMPACT System with Optional Cart and I/V Pole



SOVEREIGN™ COMPACT System Pack

Each phacoemulsification procedure requires a disposable OPO60 Tubing Pack or a sterilized OPO65 reusable Tubing Pack. The OPO60 Tubing Pack contains the following components, some of which are identified in Figure 2.2:

- Tubing manifold with irrigation and aspiration tubing
- Drain Bag - attached and sealed
- One Tip Cap Sleeve
- Test Chamber - for testing and protecting Phaco Tips and I/A Handpiece Tip
- Mayo Stand Drape - to cover the instrument tray and arm

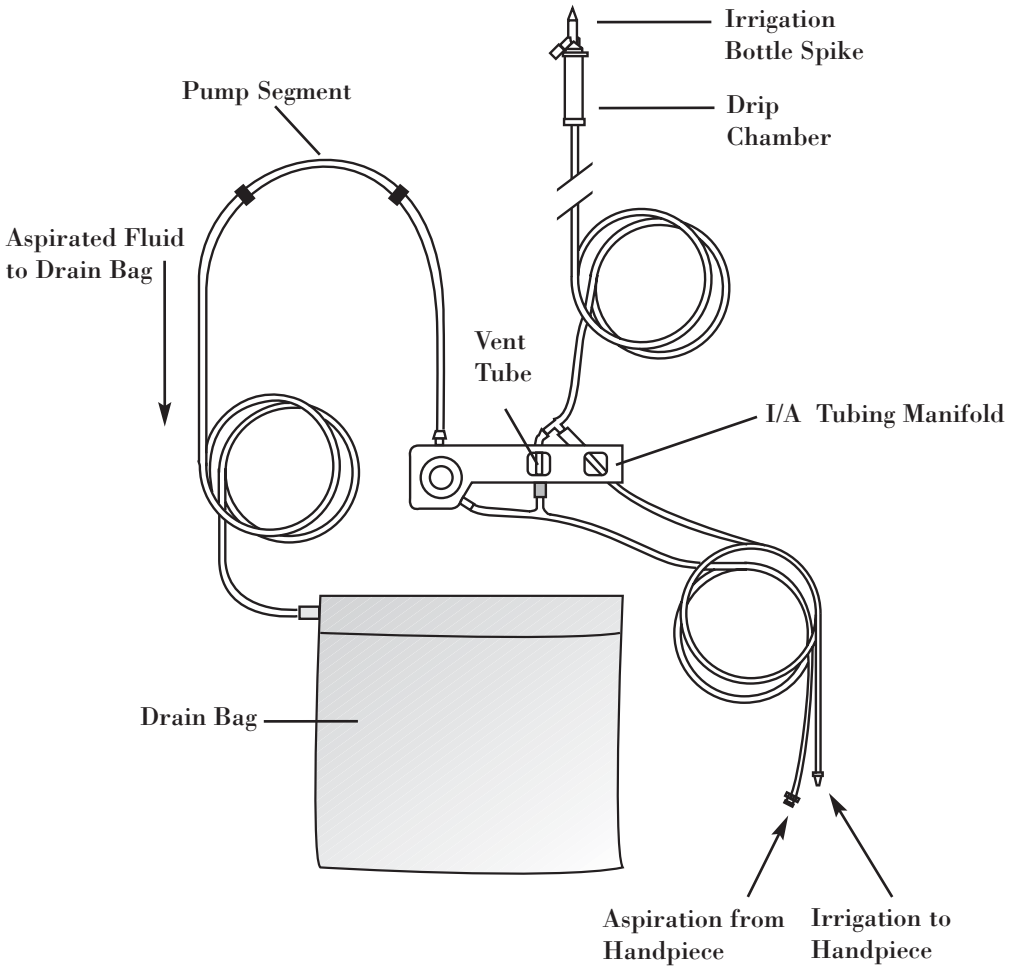
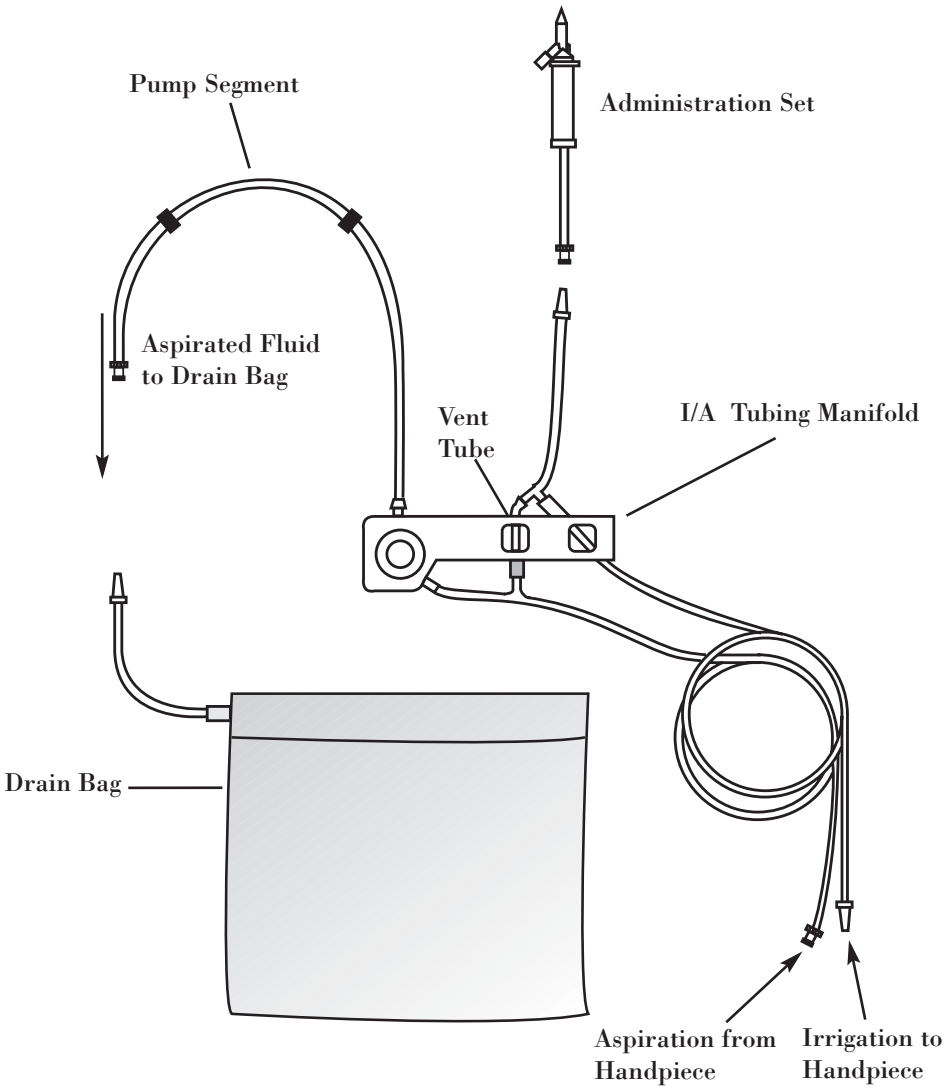


Figure 2.2
OPO60 Tubing Pack

The OPO65 Tubing Pack consists of a tubing manifold with irrigation and aspiration tubing. The pack is joined with a drain bag and administration set.

Figure 2.3

OPO65 Tubing Pack and Tubing Assembly



Pre-Operative Sterilization

The Instrument Sterilization Procedures in Section 9 identify those SOVEREIGN™ COMPACT System instruments that must be sterilized prior to each surgical case. Recommended sterilization techniques, times and temperatures are given in Section 9. AMO recommends that you follow the sterilization guidelines to maximize the life of your SOVEREIGN™ COMPACT System instruments.

3 SYSTEM SETUP

In this section you will find:

- Safety Precautions and Warnings
- System Disposal
- Symbol Definitions
- Setup Sequence
  - Power Connections
  - Phaco Handpiece
  - Irrigation/Aspiration Handpiece
  - SOVEREIGN™ COMPACT System Pack
  - Diathermy
  - Vitrectomy

Before proceeding with system setup, thoroughly read the following safety precautions and familiarize yourself with the symbols found on the back of the SOVEREIGN™ COMPACT System.

SAFETY PRECAUTIONS

1. The SOVEREIGN™ COMPACT System is equipped with 3-prong plugs which should be plugged into an outlet with a ground receptacle. If the plug does not fit the outlet, contact an electrician. DO NOT defeat or remove the ground pin.
2. Do not use extension cords with your machine.
3. Do not overload your AC electrical outlet.
4. If the cord or plug is damaged, do not continue using the instrument. Electric shock or fire hazard may result. Call AMO to order a new cord.
5. The instrument has ventilation openings to allow the release of heat generated during operation. If these openings are blocked, heat buildup can cause system failures which may result in a fire hazard.
6. Do not try to roll the SOVEREIGN™ COMPACT System cart on deep pile carpets or over objects on the floor such as cables and power cords.
7. Do not place the instrument on uneven or sloped surfaces.
8. Do not use disposables, accessories or other surgical instruments that are not designed for this system. Use only parts recommended by AMO to achieve optimum performance and safety.
9. Do not exceed maximum weight of 25 pounds (11.25 Kg) on the Programmable IV Pole bottle holder.
10. To protect patient from contaminated fluids or handpieces, use only:
    - sterile tubing sets
    - sterile irrigation fluid
    - sterile handpieces
11. Use caution when extending, retracting or swiveling the mayo stand articulating arm. Stay clear of hinged hardware.
12. Use caution when handling handpieces with sharp edges or pointed tips.
13. When using OPO65, always replace the drain bag with a clean bag between cases.
14. Wrap the excess power cord neatly around the cord wrap on the back of the I/V pole or cart.
15. Electrode cables and accessories should be regularly inspected for possible damage to the insulation. This includes the Diathermy, EVIT and Phaco cables.

- The SOVEREIGN™ COMPACT System meets ETL (Laboratory 2601.1), I.E.C. (International Electromechanical Commission) 601-1 and E.M.C. (Electromagnetic Compatibility) requirements for this type of device.
- Page 1-3 contains the Declaration of Conformity for the SOVEREIGN™ COMPACT System.

WARNINGS

WARNING: All personnel should read and understand the instructions in this manual before the system is used. Failure to do so may result in the improper operation of the system. This device is only to be used by a trained licensed physician.

WARNING: DO NOT attempt to use the system if it fails to perform properly as stated in this manual.

WARNING: DO NOT use the system in the presence of flammable anesthetics, or other flammable gases, near flammable fluids or objects, or in the presence of oxidizing agents, as fire could result.

WARNING: This unit may interfere with any cardiac pacemaker fitted to the patient, therefore qualified advice should be obtained prior to such use.

WARNING: The patient should not come into contact with metal parts which are earthed or have appreciable capacitance to earth. The use of an antistatic mat for this purpose is recommended.

WARNING: Monitoring electrodes or other types of equipment should be placed as far from those of the SOVEREIGN™ COMPACT System as possible. High current limiting devices are recommended for the protection of such systems.

WARNING: The output power selected should be as low as possible for the intended purpose.

WARNING: Although this unit complies with all EMI standards and requirements, it is possible that this unit could interfere with other types of electronic equipment.

Continued on next page

WARNINGS

WARNING: Skin to skin contact on the patient, e.g., between the arms and the torso is not recommended.

Note: The unit contains no neutral electrode.
Note: The diathermy output is bipolar.
Note: It is recommended that the condition of all inter-connecting and handpiece cables be checked on a regular basis.

WARNING: Risk of burns and fire. Do not use near conductive materials such as metal bed parts, inner spring mattresses, and the like. Renew electrode cables on evidence of deterioration.

WARNING: Hazardous electrical output. This equipment is for use only by qualified personnel.

WARNING: Disconnect power before servicing.

WARNING: Not recommended for use in condensing environment. If exposed to condensing environment, allow system to equilibrate to typical operating room conditions prior to use.

WARNING: This HIGH FREQUENCY (HF) SURGICAL EQUIPMENT is specified for use without a NEUTRAL ELECTRODE.

WARNING: Failure of the HIGH FREQUENCY (HF) SURGICAL EQUIPMENT could result in an unintended increase of output power.

WARNING: Interference provided by the operation of the HIGH FREQUENCY (HF) SURGICAL EQUIPMENT may adversely influence the operation of other electronic equipment.

SYSTEM DISPOSAL

The electronic components of the SOVEREIGN™ COMPACT System are subject to the European Union Directive 2002/96/EC on Waste Electrical and Electronic Equipment. This directive applies to all electronic equipment in the European Union only.

The disposal to municipal waste is prohibited for electronic equipment subject to this directive; this equipment must be treated or recycled. Each component that is subject to this regulation is marked on the component itself with the following symbol:

In some cases where the component's size prohibits marking (such as handpieces) the marking can be found on the directions for use and the warranty.

Treatment and/or recycling of the electronic equipment is provided at no cost to you. Please see the contact information below for disposition of unwanted AMO electronic equipment.

For disposal of your unit, contact your local AMO subsidiary or the AMO service center.

AMO Germany GmbH
Surgical Systems Service
+49 7243 729 444 (Hotline)
SE_Service@amo-inc.com

AMO France SAS
Mougins/France
Phone: +33 49 22 87 228

AMO Italy Srl
Rome/Italy
Phone: +39 06 51 29 61

AMO Netherlands B.V.
Nieuwegein/Netherlands
Phone: +31 30 75 03 740

AMO Norden AB
Vantaa/Finland
Phone: +358 9 8520 2192

AMO Norden AB
Upplands Vasby/Sweden
Phone: +46 8594 21 000

AMO Spain S.L.
Madrid/Spain
Phone: +34 9176 88 000

AMO Switzerland GmbH
Lachen/Switzerland
Phone: +41 554 51 07 80

AMO UK Ltd
Woodburn Green/
United Kingdom
Phone: +44 162 85 51 600

Symbol Definitions

The following symbols appear on the SOVEREIGN™ COMPACT System front and back panels:

Symbol on power switch indicates Power is ON.

Symbol on power switch indicates Power is OFF.

Indicates that there are important operating and maintenance instructions included in the Owner's and Operator's Manual.

Indicates the presence of uninsulated high voltage inside the instrument. Risk of electric shock. Do not remove the instrument cover.

Indicates fuse.

Single phase alternating current.

Patient applied part is isolated from earth ground.

Patient applied part is grounded OR no direct electrical energy is involved.

Foot Pedal connection.

Communications Port

Remote

Programmable Power Pole

Diathermy Forceps

Phaco Handpiece Receptacle

TAC Cutter (Oscillating)

Potential Equalizer

Indicates compliance with the Medical Device Directive

Separate Collection Required

Indicates product listed with Intertek Testing Services

Indicates compliance with IEC 60601-1-2:2001, "Electromagnetic Compatibility Requirements and Tests for Medical Electrical Equipment"

Environment Friendly Use Period, in Years

Below the hazardous materials limits in SJ/T11363-2006 (China)

Setup Sequence

The following is a general overview of the steps to be taken to prepare the SOVEREIGN™ COMPACT System for surgery:

1. Connect the power.
2. Turn the system on.
3. After completion of the Start Up test, select the surgeon program.
4. Attach the intended accessories and set up the tubing.
5. Prime and tune the handpiece.
6. Perform the final test of fluidics and handpiece integrity with the footpedal.

Power Connections

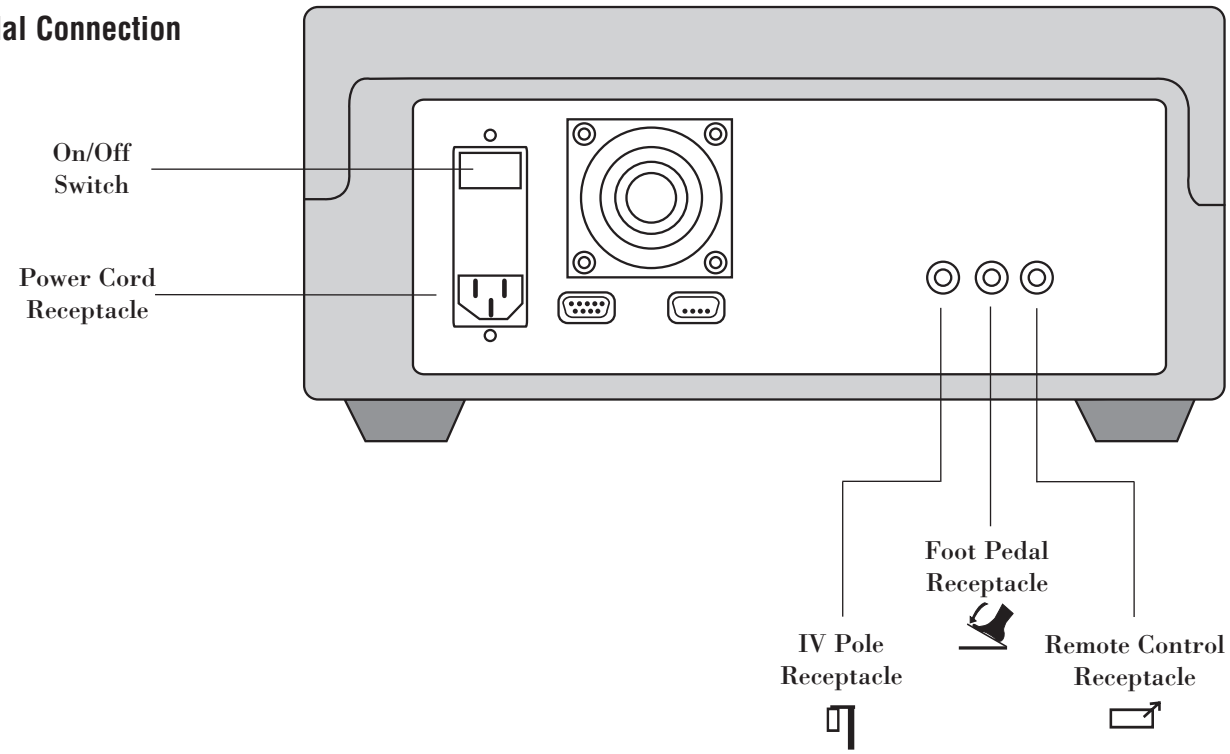
1. **Connect the Foot Pedal** to the back of the SOVEREIGN™ COMPACT System console (see Figure 3.1) Once connected, the foot pedal can be stored in the bottom storage bin of the cart without disconnecting.

2. **Connect the Remote Control** to the receptacle on the back of the console (see Figure 3.1).

3. **Connect the SOVEREIGN™ COMPACT System power cord** to the rear of system. Plug the power cord into a grounded power outlet.

4. Turn the system ON.

Figure 3.1
Foot Pedal Connection



Phacoemulsification Ultrasonic Handpiece

Warning: Sterility assurance is the responsibility of the user. All non-sterile accessories should be sterilized prior to use.

Warning: Prior to using any invasive portions of the handpiece assembly, examine under the microscope for any obvious damage, oxidation, or the presence of foreign material. If any questionable characteristics are noted, use a backup handpiece for surgery. Use of contaminated or damaged system accessories may cause patient injury.

1. **Take caution to prevent burns** when handling the handpiece(s) directly from sterilization.

2. **Remove the tubing manifold and accessories** from the tubing pack and place them in the sterile area.

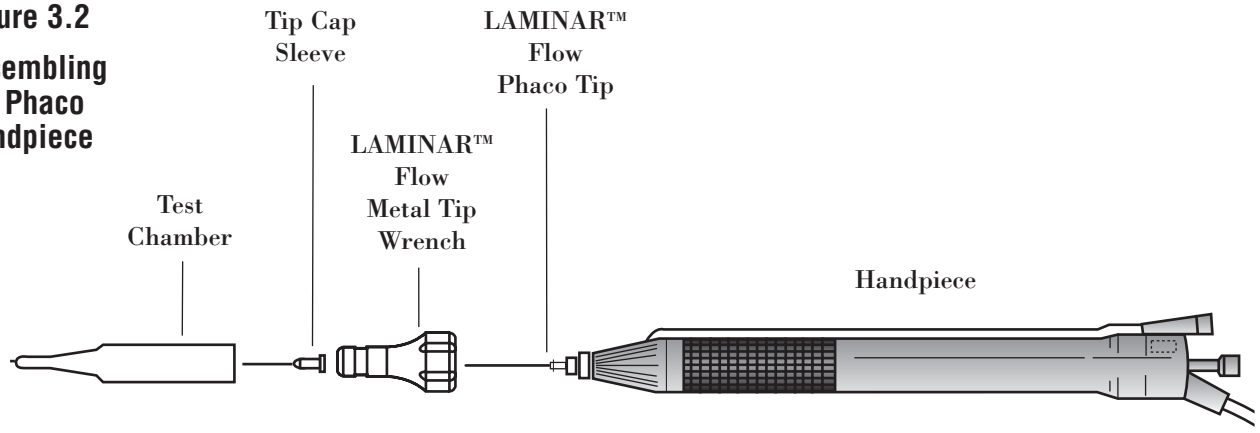
3. **Assemble the ultrasonic handpiece** as shown in Figure 3.2. You will need the handpiece, titanium phaco tip, the appropriate tip wrench, the tip cap sleeve and the test chamber.

CAUTION

NEVER ATTEMPT TO STRAIGHTEN A BENT NEEDLE. THIS WILL PRODUCE A BROKEN TIP WHEN PHACO IS APPLIED.

Figure 3.2

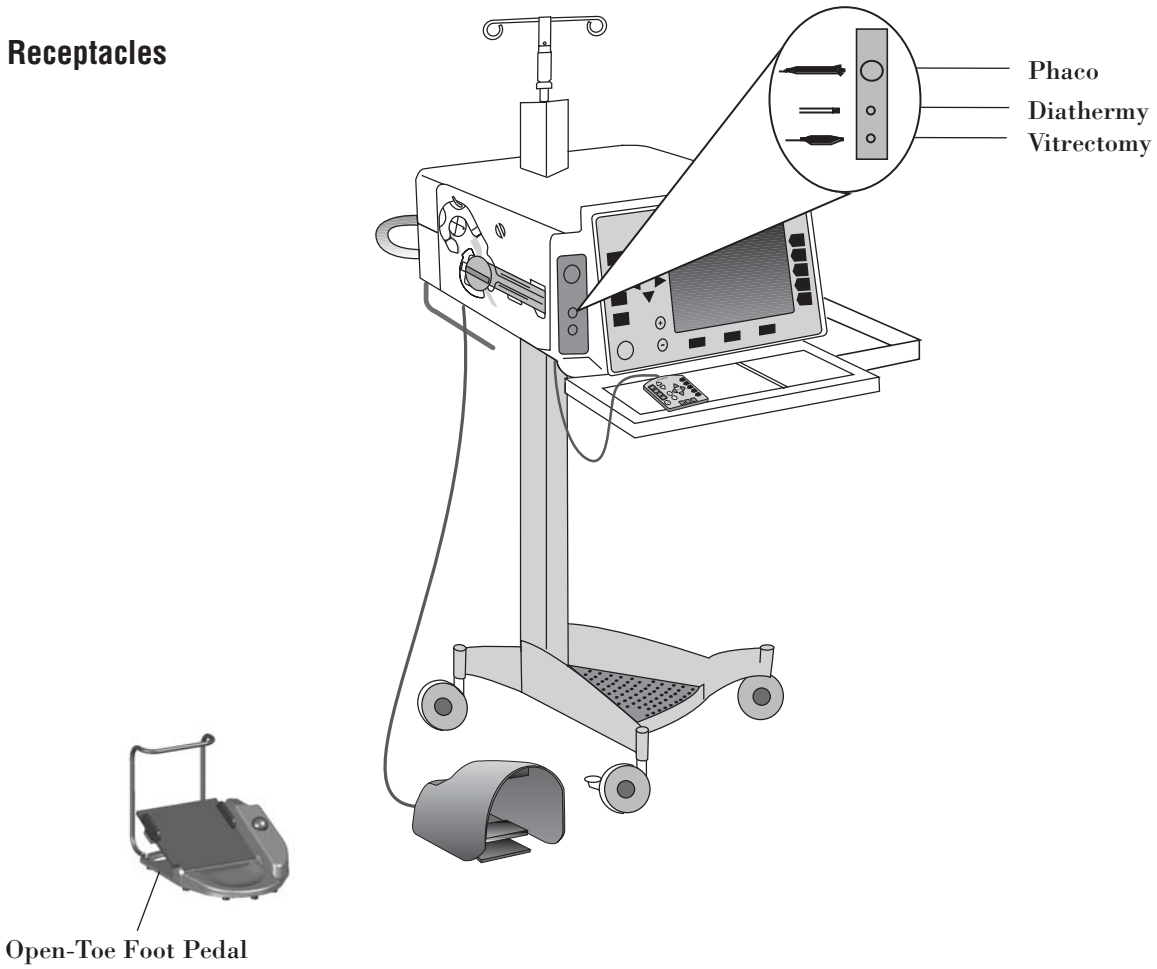
Assembling the Phaco Handpiece



4. **Attach the connector end of the handpiece** to the phaco receptacle on the front of the SOVEREIGN™ COMPACT System, shown in Figure 3.3.

   Make sure that there is no moisture on the connectors prior to connecting. Moisture will prevent the handpiece from operating properly.

Figure 3.3
Handpiece Receptacles

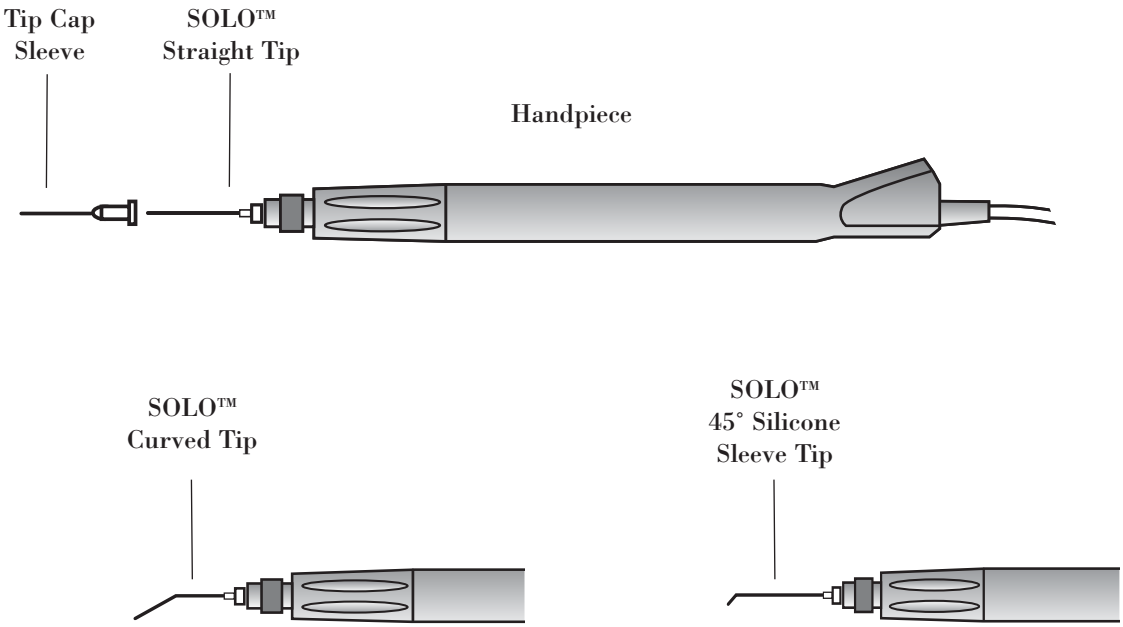


Irrigation/Aspiration Handpiece

1. **Assemble the SOLO™ Irrigation/Aspiration (I/A) Handpiece** by attaching the tip cap sleeve*.

   - Irrigation sleeve and test chamber are found in the SOVEREIGN™ COMPACT System Pack, OPO60.
   - The LAMINAR™ Flow 20 ga. irrigation sleeves may also be used and are available with the OPOS20L or any 20 ga. LAMINAR™ Phaco Tip.

Figure 3.4
SOLO™ I/A Handpiece



Load the Tubing Manifold

1. Open the OPO60 Tubing Pack, illustrated in Figure 3.5, and take out the I/A Tubing Manifold.

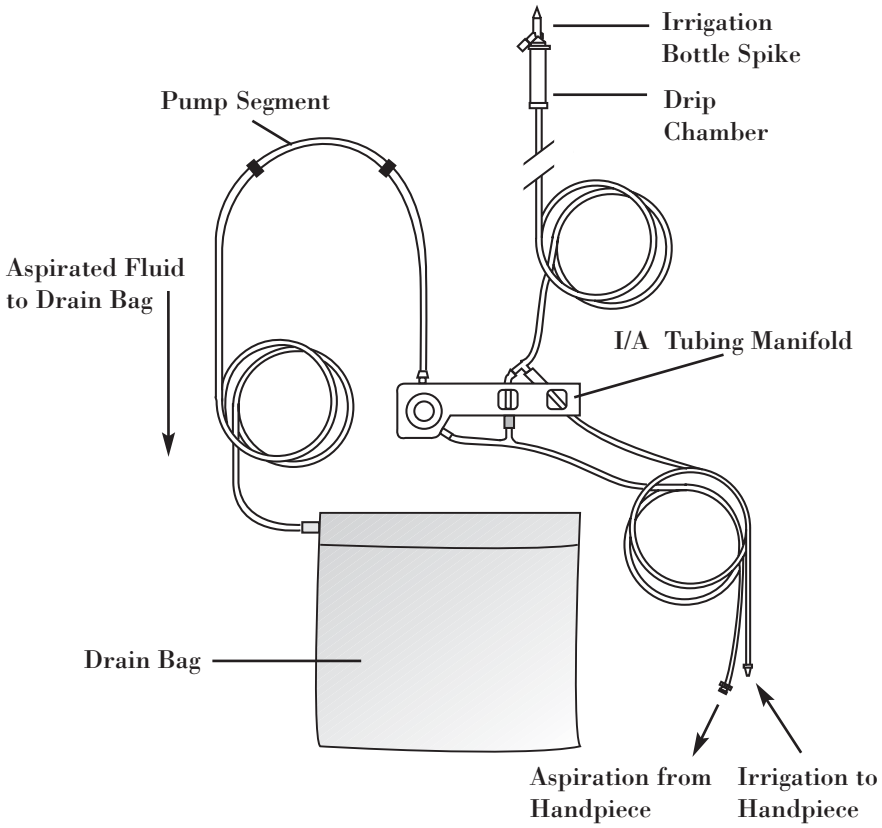


Figure 3.5
OPO60 Tubing Pack

2. Open the pump latch, and release the manifold latch as shown in Figure 3.6.

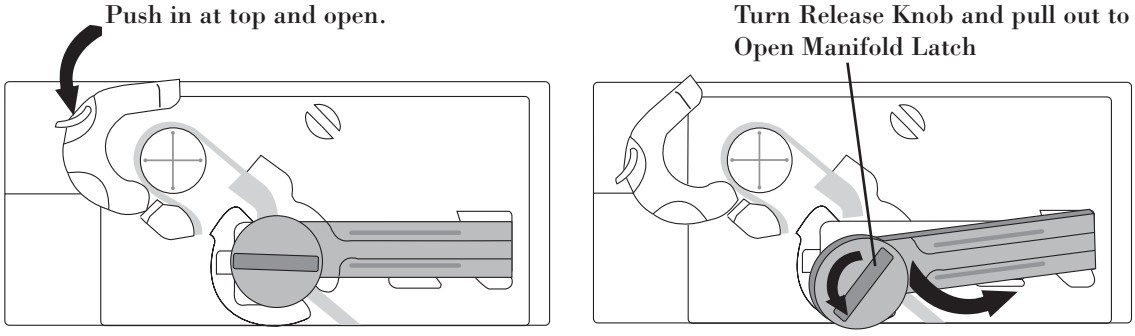


Figure 3.6
Opening the Pump Latch and Releasing the Manifold Latch

Figure 3.7

Positioning the I/A Tubing Manifold in the Pump

- Insert the irrigation line into the guidance slot.

3. Position the I/A tubing manifold in the pump manifold leaving latch open.

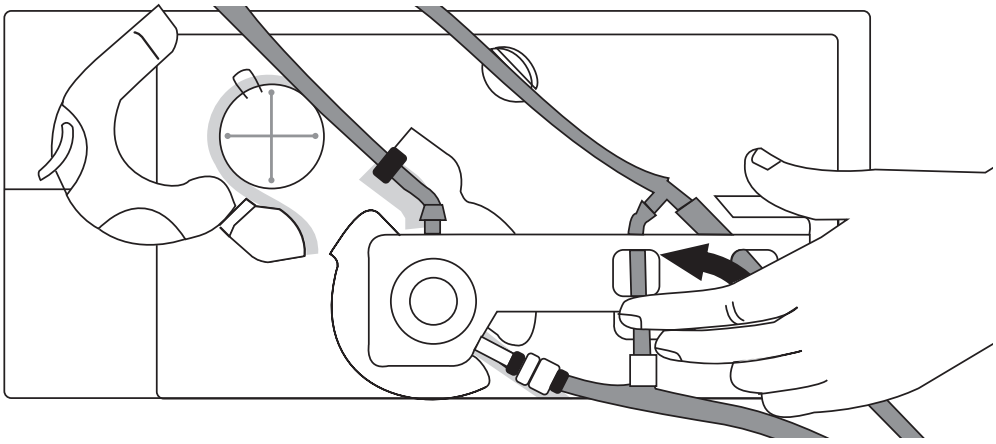


Figure 3.8

Pump Segment Installation (part 1)

- Insert the pump segment.
- Install the pump segment onto the peristaltic pump.
- First, place the collar closest to the manifold onto the pump.
- Depress collar into recess using index finger.

4. Load the pump segment as shown in Figures 3.8 and 3.9 and close the pump latch.

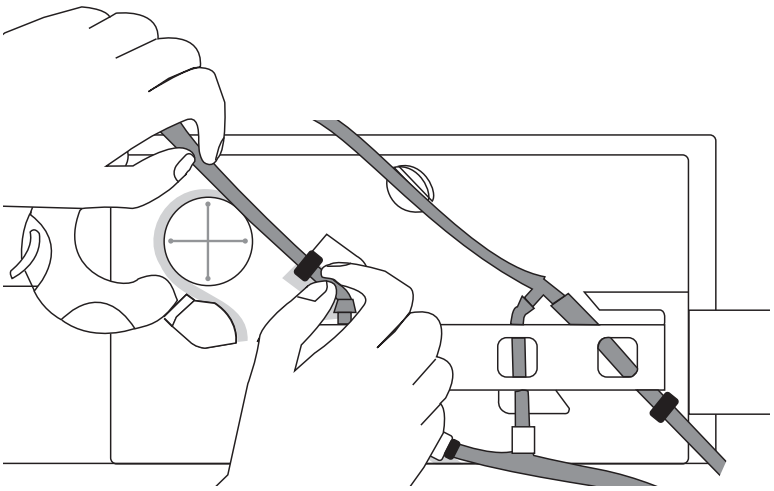
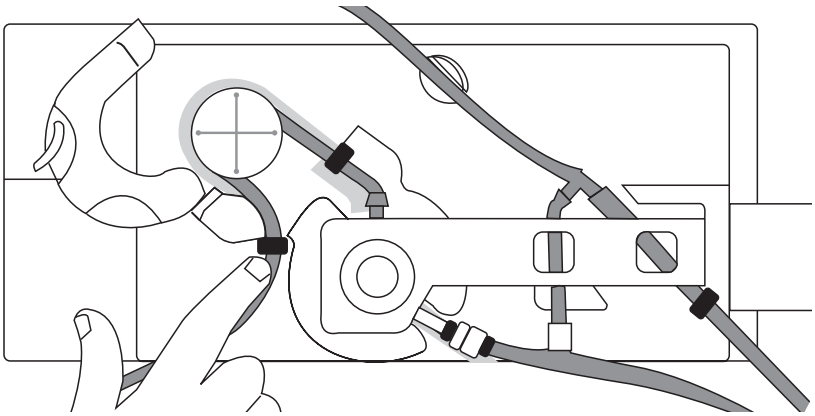


Figure 3.9

Pump Segment Installation (part 2)

- Stretch the pump segment over the rollers. Ensure that tubing is aligned in the center of the rollers.
- Depress second collar into recess using index finger.
- Close the pump latch. The latch should snap closed. (see Figure 3.10)

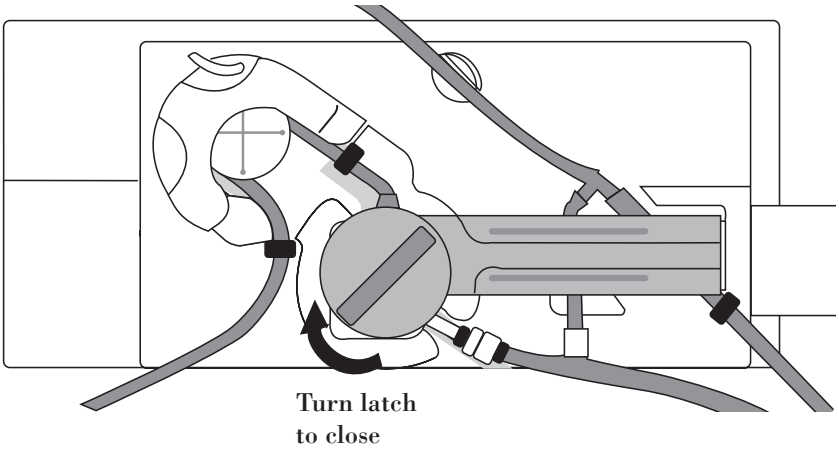


5. Close the manifold latch to prepare system for priming as shown in Figure 3.10.

Figure 3.10

Maniold Latch Closed and Prepared for Priming

- Close the manifold and turn the release knob to latch the manifold closed.



6. Attach drain bag as shown in Figure 3.11.

Figure 3.11

Attach Drain Bag

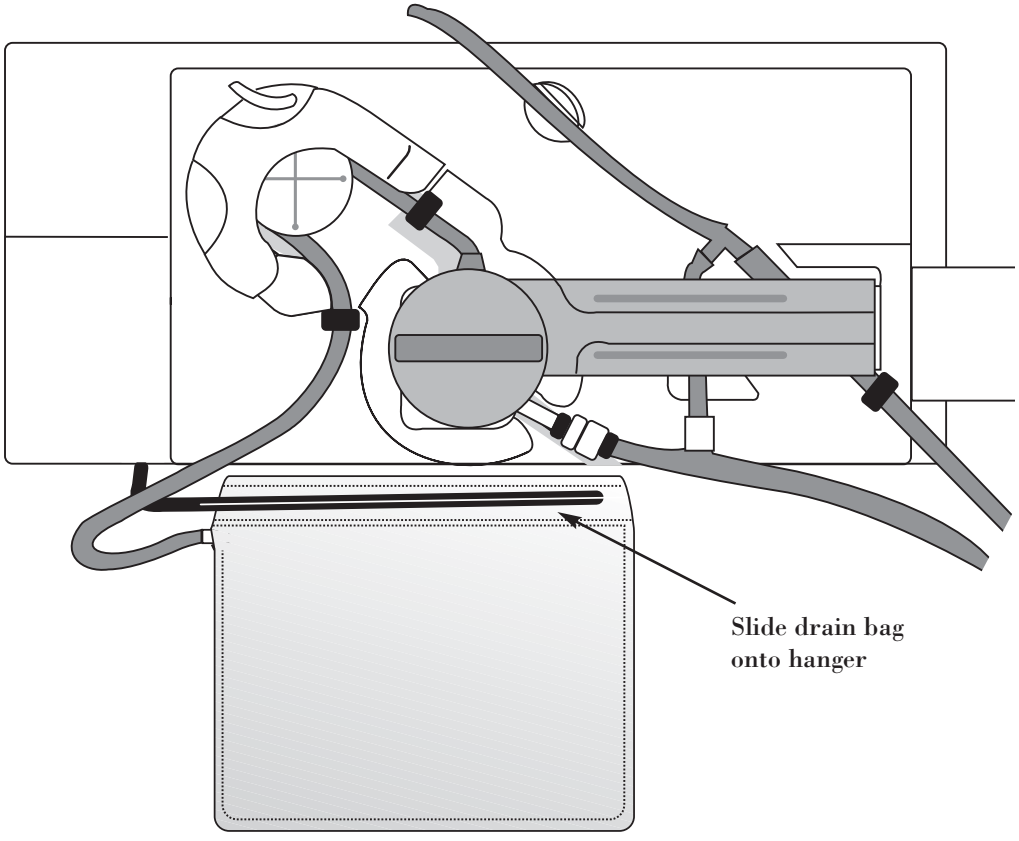
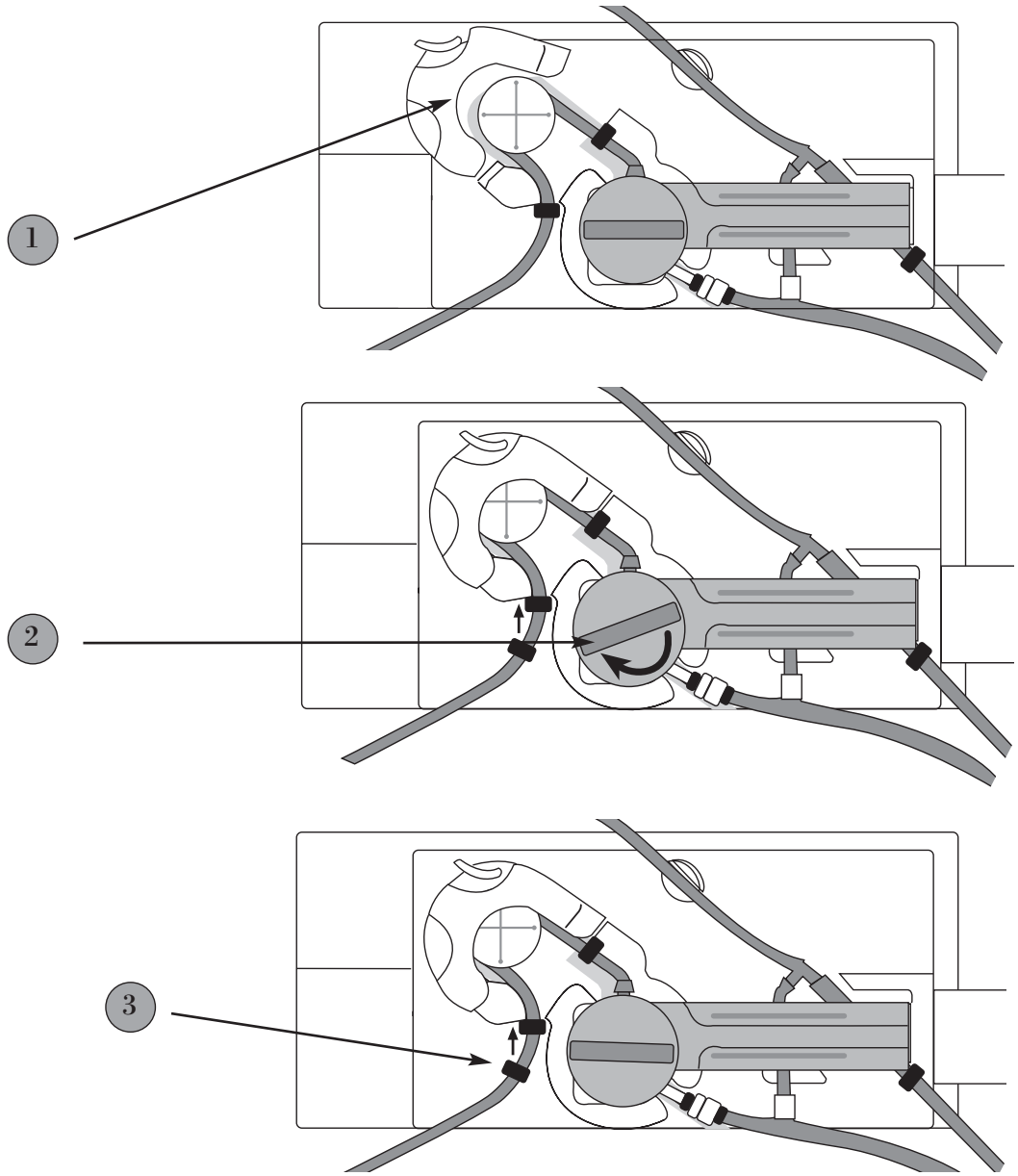


Figure 3.12

Installation Troubleshooting Watchouts

7. Review installation for troubleshooting watchouts as shown in Figure 3.12.



The arrows show common causes of error messages:

1. Failure to completely close pump latch - this can be the result of tubing not centered on the roller and "bunched-up" in the area of the hinge.
2. Manifold latch not closed - this can be caused by the manifold release knob not being closed completely, or from the tubing which was not completely seated into the manifold - do not force the latch closed.
3. Note that the blue "stop" is pulled down too far in the channel. This can cause "pump rotation" error messages.

Complete Setup

Note: To protect the patient from contamination, use only:

- ***sterile tubing sets***
- ***sterile irrigation fluid***
- ***sterile handpieces***

1. **IMPORTANT!** Before stabbing the bottle, shake the irrigation drip chamber at the end of the irrigation tubing to confirm that the irrigation check valve rattles freely. If the valve does not rattle, it may not operate properly and irrigation may not flow.

2. Place a new bottle of balanced salt solution on the spike mat on top of the system console. Insert (spike) the drip chamber into the balanced salt solution bottle.

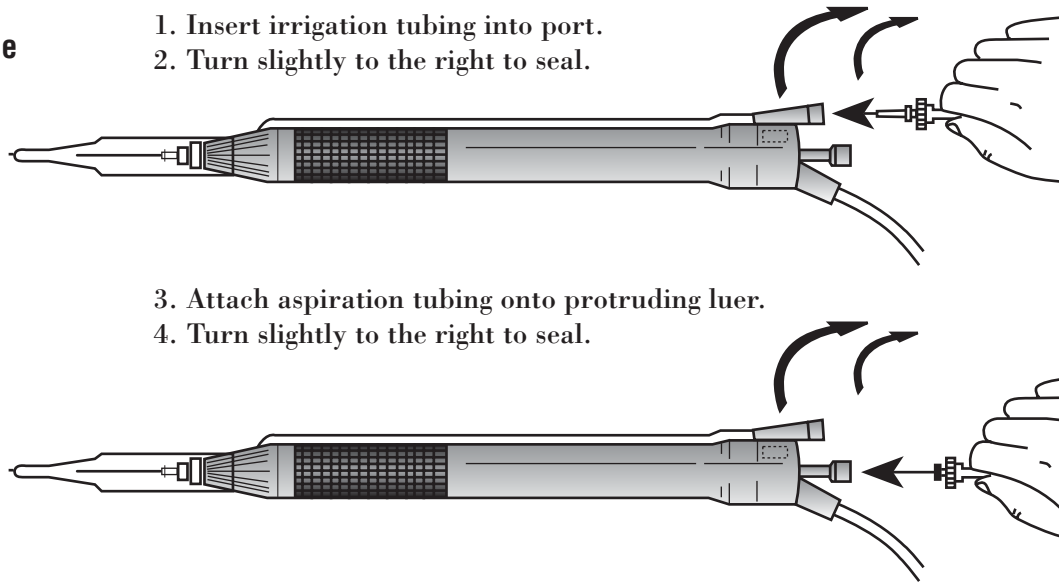
3. **Hang the balanced salt solution bottle from the Programmable IV Pole and squeeze the drip chamber. Fill with fluid to the half-full level.** The IV Pole will move to the appropriate height automatically. However, if a manual pole is used, set the fluid level in the drip chamber at approximately 65 cm above the patient's eye level. Raise or lower the pole as required using the IV pole +/- push-buttons on the front panel.

4. **Hang the drain bag (attached to the end of the aspiration tubing)** on the holder on the left side of the SOVEREIGN™ COMPACT System cart or console. See Figure 3.11.

5. **Connect the I/A tubing to the ultrasonic handpiece.**
   - Insert the male luer end of the irrigation tubing into the ultrasonic handpiece, as shown in Figure 3.13.
   - Attach the female luer fitting end of the aspiration tubing to the ultrasonic handpiece.

Figure 3.13

Attaching I/A Tubing to the Phacoemulsification Ultrasonic Handpiece


1. Insert irrigation tubing into port.
2. Turn slightly to the right to seal.
3. Attach aspiration tubing onto protruding luer.
4. Turn slightly to the right to seal.

The I/A tubing may be connected to the I/A handpiece in the same manner as described in step 5 above.

Diathermy

1. **Connect the Diathermy Forceps and Cord.** Connect the diathermy forceps to the diathermy cord as shown in Figure 3.14, then connect the diathermy cord to the diathermy receptacle on the console left side (shown in Figure 3.3).

Figure 3.14
Connecting the Diathermy Forceps

NOTE: Other diathermy accessories may be regionally available. See your AMO representative.

Vitrectomy

Vitrectomy requires an AMO™ Vitrectomy Handpiece. The OM0201011D Vitrectomy Handpiece (Oscillating) is reusable.

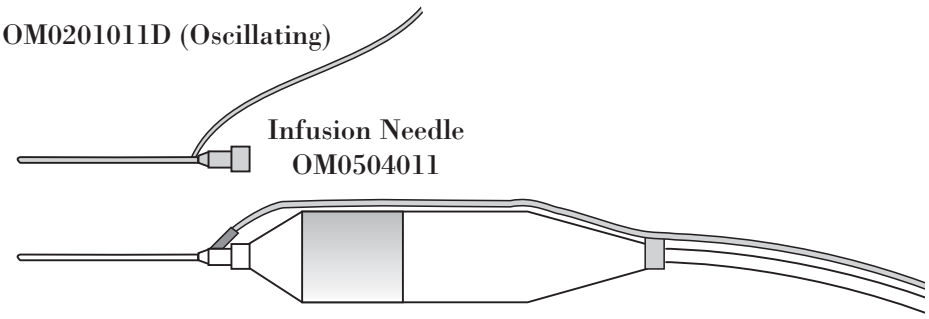
If vitrectomy is indicated during surgery:

1. **Connect the AMO™ Vitrectomy Handpiece** as shown in Figure 3.15. Vitrectomy requires the following components:

   • I/A Tubing (from OPO60 or OPO65)
   • Vitrectomy Handpiece
   • Vitrectomy Infusion Sleeve, or 23 Gauge Limbal Infusion Needle, if desired.

   Assemble the handpiece using the instructions provided with the vitrectomy handpiece.

Figure 3.15
AMO™ Vitrectomy Handpiece



Connect the connector end of the vitrectomy cord to the vitrectomy receptacle on the console left side (shown in Figure 3.3).

4 EQUIPMENT OPERATION

This section provides descriptions and operational instructions for:

- Foot Pedal
  - Foot Pedal Positions
  - Reflux
  - Mode Change with Foot Pedal
- Programmable Power Pole
- Display Screen and Controls
- Selecting and Changing Modes and Parameters
- Remote Control

Foot Pedal

The foot pedal controls all of the SOVEREIGN™ COMPACT System functions, therefore, it is essential that you understand its operation.

The following options and adjustments may be selected and preset for the foot pedal:

- Threshold = FP1, FP2, FP3
- Vitrectomy = IAC OR ICA foot pedal positions, Side Vit

Instructions for foot pedal parameter settings will be given in Section 6.

Figure 4.1
Foot Pedal

Figure 4.1 A: Open-Toe

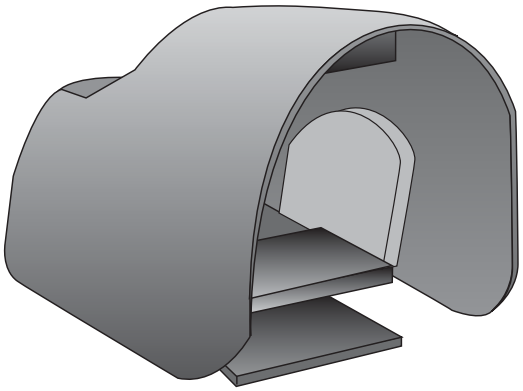


Figure 4.1 B: Closed-Toe

Note: You should never handle the foot pedal by its power cable.

Foot Pedal Operation

The foot pedal has 3 active ranges, which are referred to as positions 1, 2 and 3. Position 0 is the OFF position. These ranges are shown in Figure 4.2

Figure 4.2
Foot Pedal Positions

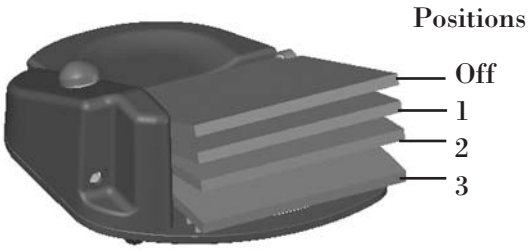


Figure 4.2 A: Open-Toe

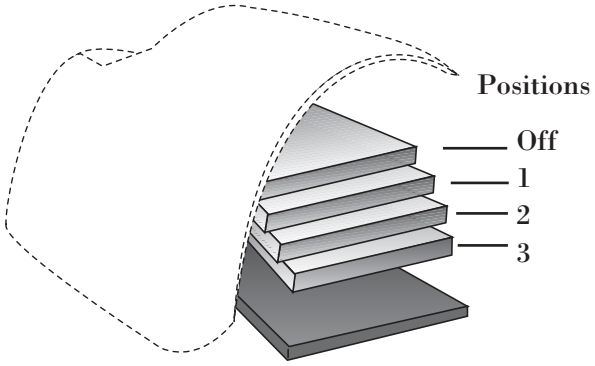


Figure 4.2 B: Closed-Toe

The foot pedal position determines the function that will be delivered by the handpiece, which depends on the mode selected on the front panel (Diathermy, Phaco, Irrigation/Aspiration, or Vitrectomy). The foot pedal display in the upper right corner of the screen indicates foot pedal position (0, 1, 2, or 3). The functions of each position are described in Figure 4.3.

Figure 4.3

Handpiece Functions in Foot Pedal Positions

Foot Pedal Postions	Modes: Diathermy	Continuous Irrigation Enabled	Phaco	Irrigation/ Aspiration	Vitrectomy IAC	Vitrectomy ICA	Vitrectomy Side VIT
0	OFF	ON	OFF	OFF	OFF	OFF	OFF
1	OFF	ON	Irr (Only)	Irr (Only)	Irr (Only)	Irr (Only)	Irr (Only)
2	↓	↓	Irr/Asp	Irr/Asp	Irr/Asp	Irr/Cut	Irr/Asp
3	↓	↓	Irr/Asp/Phaco	↓	Irr/Asp/Cut	Irr/Cut/Asp	↓

Reflux

Once the foot pedal has been connected (as described in Section 3), you simply place your foot on the pedal and depress the pedal to the desired position.

Reflux is essentially a reversal of aspirated fluid flow to assist in the release of unwanted material. Reflux is activated by pressing the foot pedal top switch. The reflux switch is turned off and on in the Settings program screen.

Figure 4.4

Foot Pedal Reflux Top Switch

Figure 4.4 A: Open-Toe

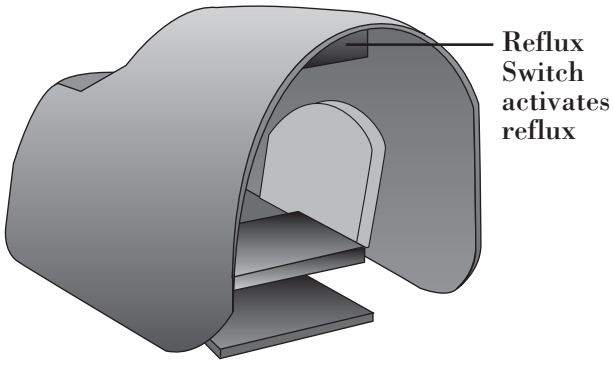


Figure 4.4 B: Closed-Toe

Reflux (Cont.)

The pinch valve opens the aspiration line to the positive bottle head pressure (dependent on IV pole height and gravity) and gently causes fluid to flow toward the handpiece. REFLUX stays on until the pinch valve is released.

Reflux should not be used to clear clogged handpieces but can be used to identify a blockage.

WARNING:

- **Reflux is a user selectable switch option. In the event of captured tissue and vacuum present, deselection of reflux requires user to release footpedal to position 0 to open vent valve.**

Sub-Mode Change with Foot Pedal Side Switches

The foot pedal side switches execute a mode change between various sub-modes. For example, you can change from Phaco 1 to Phaco 2 by the foot pedal side switch. This allows you to change submodes with the foot pedal, the same as pushing the front panel submode selection. Additional information is given in Section 5.

Figure 4.5

Foot Pedal Side Switches

Figure 4.5 A: Open-Toe

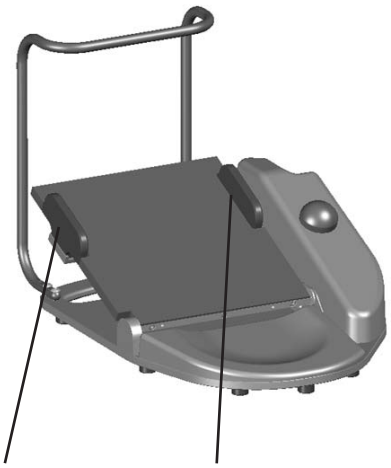
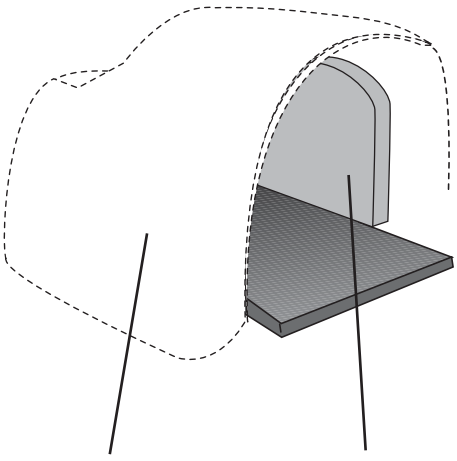


Figure 4.5 B: Closed-Toe

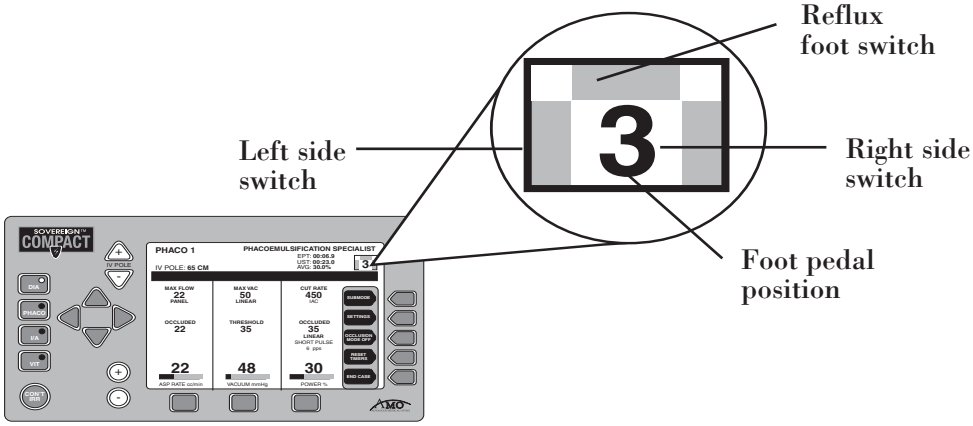


(Continued on next page)

Figure 4.6

Foot Pedal Position Indication

In the upper right corner of the display screen, the foot pedal position and foot switch(es) activated are displayed as shown in Figure 4.6.



Programmable IV Pole

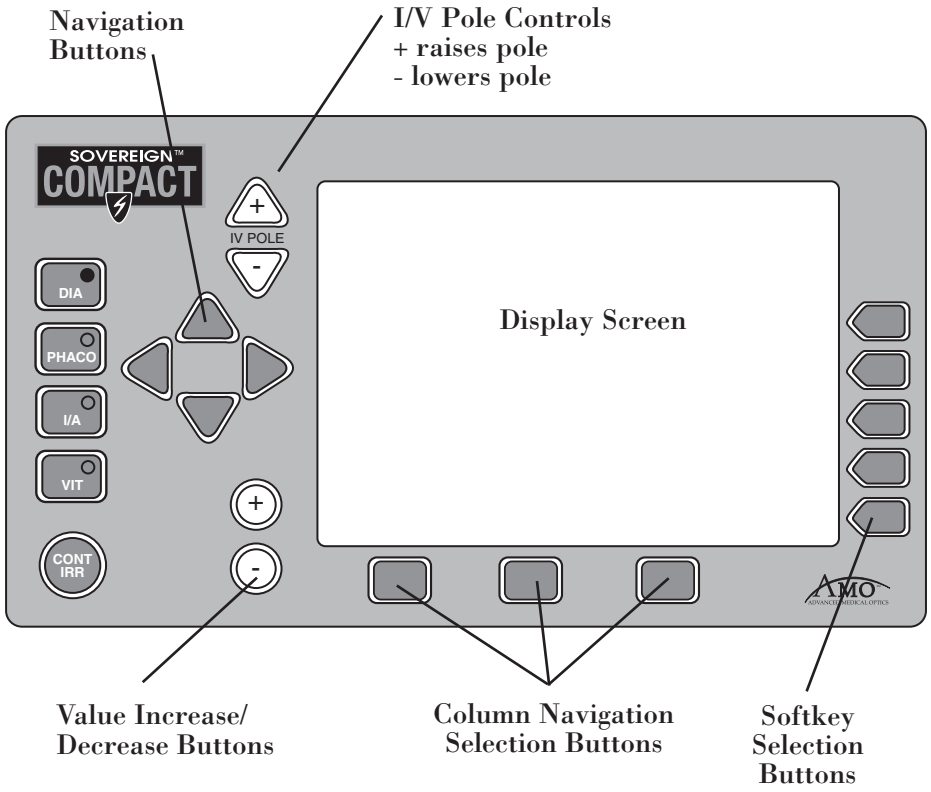
The Programmable IV Pole is controlled by the (+) and (-) IV Pole control on the front of the panel as shown in Figure 4.7. These keys are used to raise and lower the pole, and the height is indicated in the Programmable IV Pole display. The Programmable IV Pole travels at a rate of approximately 10 cm (4 inches) per second.

- **Programmable IV Pole is Adjustable from 0 to 76 centimeters. Height measurement is relative to the distance from the reflux valve to the center of the drip chamber.**

The Programmable IV Pole height is displayed in the upper left screen in centimeters after Prime/Tune or full extension of pole to top position (pole calibration). The Programmable IV Pole height for each fluidic mode (Phaco, I/A, Vit) is saved in the SOVEREIGN™ COMPACT System memory. When the mode is selected, the Programmable IV Pole will automatically travel to the preset height. Instructions for Programmable IV Pole height presets are given in Section 5, Programs. To manually adjust the IV pole height, simply press the + and - Programmable IV Pole control located on the upper left of the panel. Additionally, manual adjustment can also be made via the rocker switch on the IV pole housing.

Figure 4.7

Controls



Display Screen and Controls

The SOVEREIGN™ COMPACT System display screen and controls are used to configure the system setup, and to give visual indication of operating modes and status. The control operations are described in Figure 4.7.

Each mode and sub-mode has its own discrete screen(s) display:

- I/A
- Phaco with Occlusion Mode Off
- Phaco with Occlusion Mode On
- Vitrectomy
- Diathermy

Additionally, there are screens or sub-screens for:

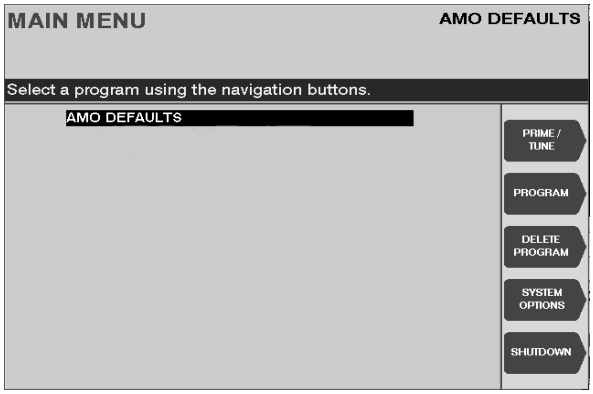
- Language Selection
- Settings
- Save Options
- Save As
- Diagnostics/Maintenance
- End Case
- Prime/Tune
- System Options
- Main Menu

Select Language

The SOVEREIGN™ COMPACT System features a 14-language multi-lingual user interface. Before proceeding, select one of the languages for your display screen and controls. (English is the default language).

Figure 4.8

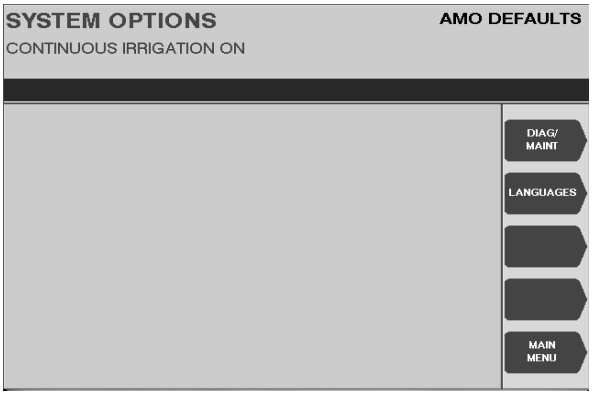
Select SYSTEM OPTIONS



1. From the MAIN MENU select SYSTEM OPTIONS.

Figure 4.9

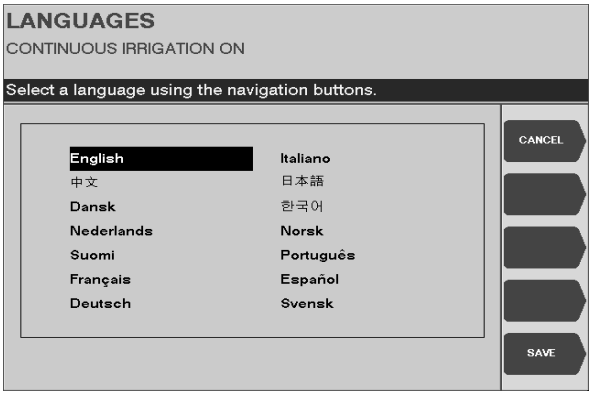
Select LANGUAGES



2. From SYSTEM OPTIONS select LANGUAGES.

Figure 4.10

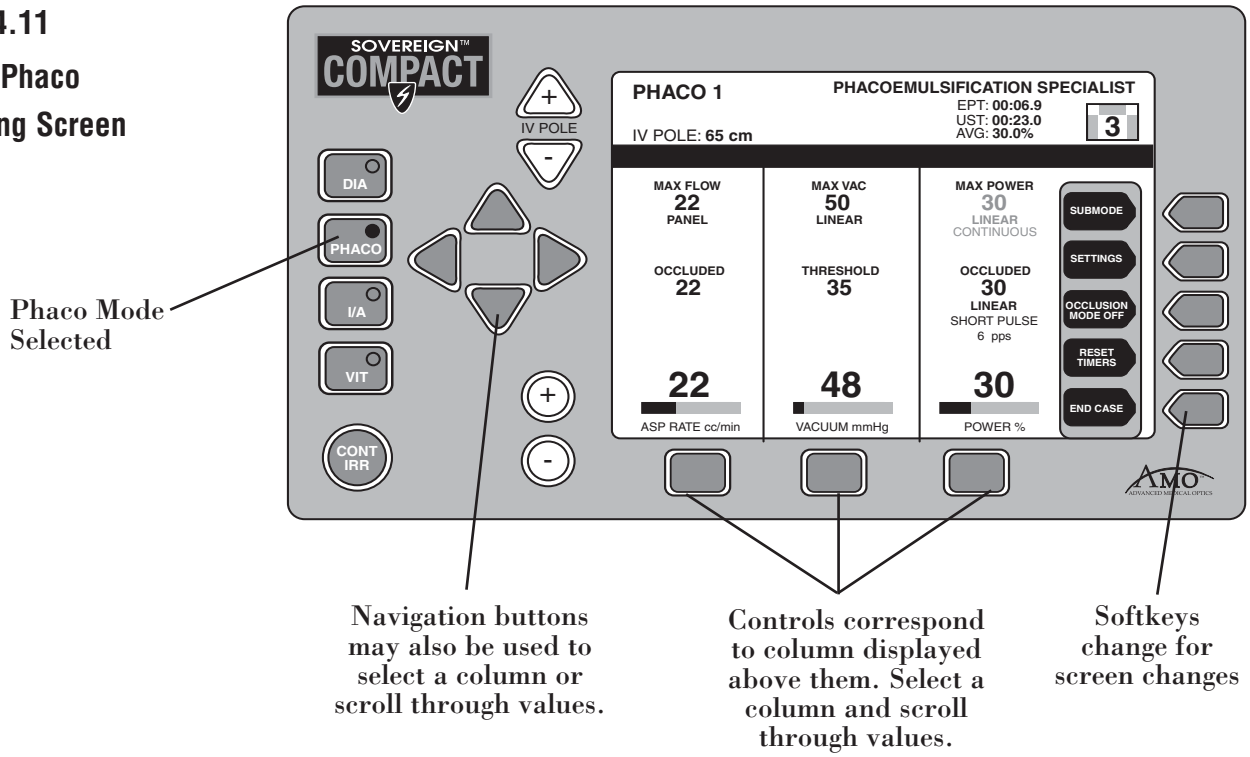
Select and SAVE Language



3. Use Navigation buttons to select language.
4. PRESS SAVE

Note: If the system powers up in a language you do not understand, go to Troubleshooting, page 10-7 for instructions.

Figure 4.11
Typical Phaco Operating Screen



Selecting and Changing Modes and Parameters

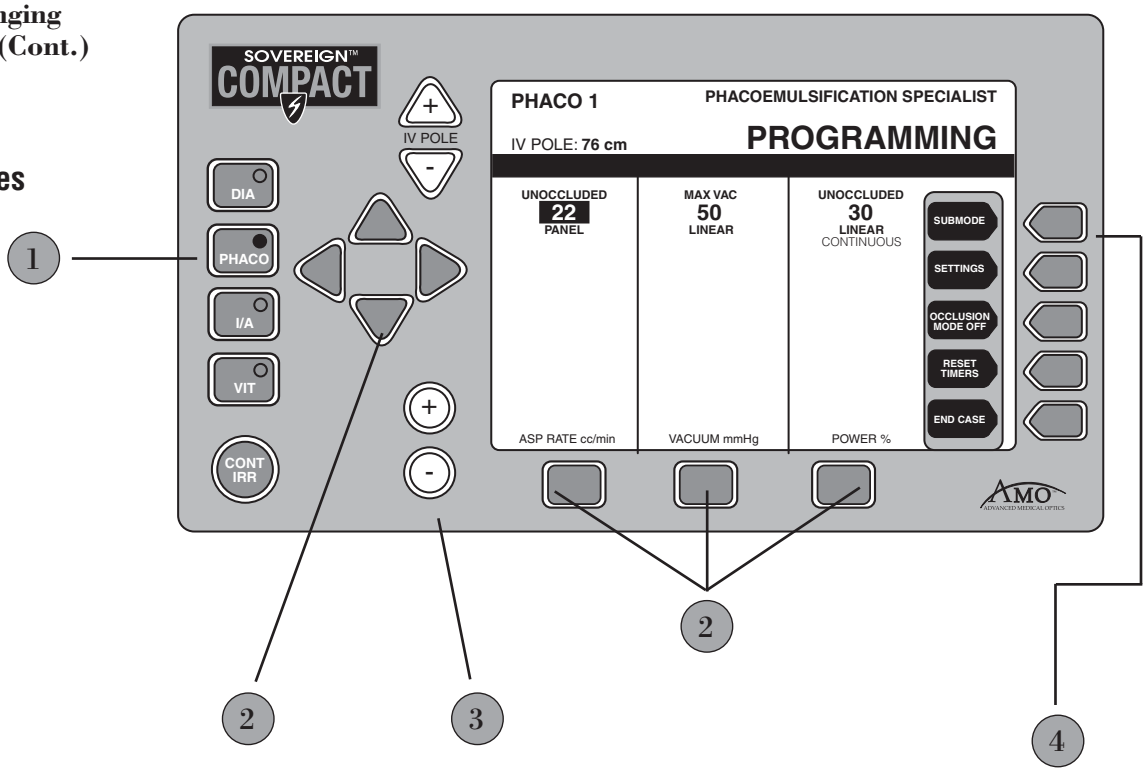
The system's user interface is designed for ease-of-use, consistent application and maximum informational display during all operating modes. The user interface with the system requires only three basic steps, which apply to all of the selections, settings and operations. Once this basic organization is understood, you should be able to move quickly and easily through all of the system functions and operations:

1. The display screen is organized into columns, and the controls below each of these columns allow you to select the parameter or function displayed above it.
2. Within each column there are individual settings and selections that may be accessed by moving the "selection box" to highlight the desired setting. To move the selection box, use the navigation buttons or column select keys.
3. Once the desired parameter/setting is highlighted, the setting may be adjusted using the + and - value adjust buttons.

Selecting and Changing Mode Parameters (Cont.)

Figure 4.12

Programming Modes



To select a Mode and change a parameter:

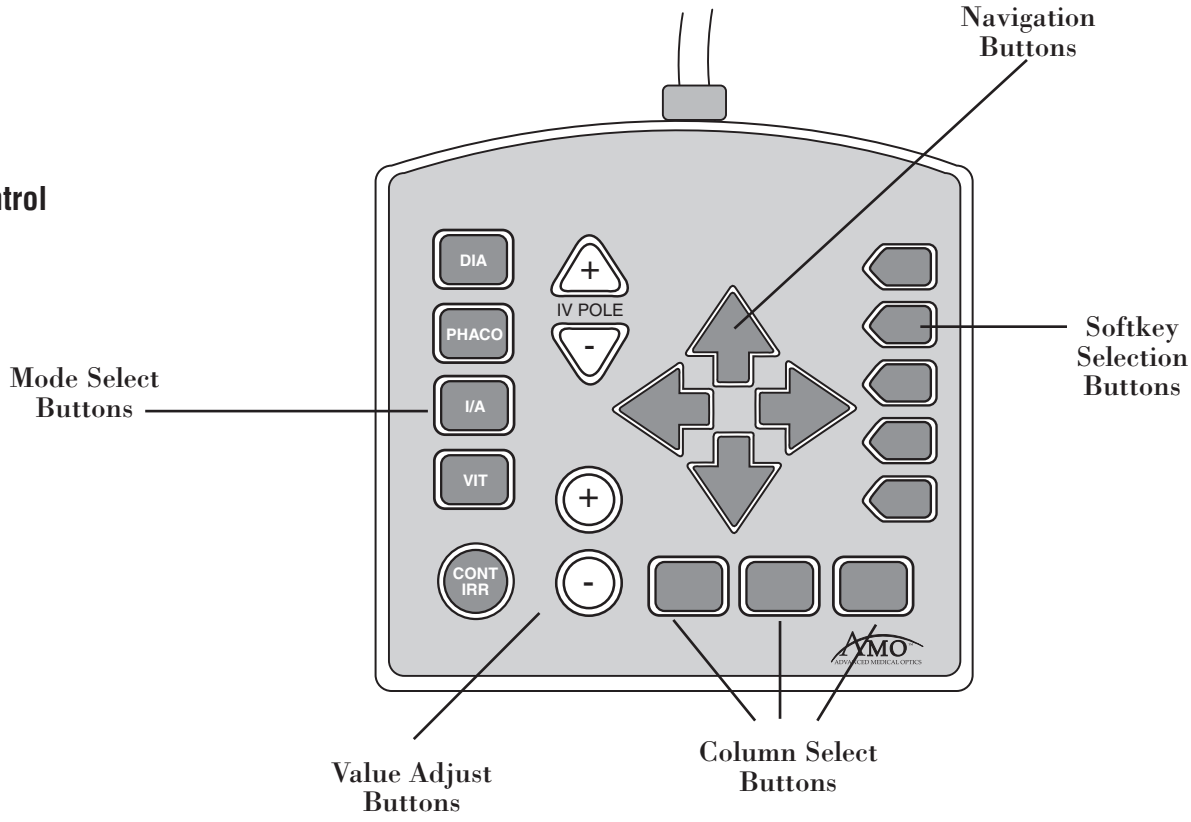
1. Press the Mode button to select the desired mode.
2. Select the parameter using navigation buttons or column select buttons.
3. Press the Value Adjust button to change the parameter value.
4. Select Sub-Mode to program next Sub-Mode (if present).

Remote Control

Operation of the SOVEREIGN™ COMPACT System is also selectable from the remote control keypad. All Modes, Programs, Testing and End Case may be accessed and adjustments to the settings can be made from the remote. The buttons on the Remote keypad function identically to the buttons on the SOVEREIGN™ COMPACT console.

Figure 4.13

Remote Control Keypad



5 PROGRAMS

This section provides instructions on how to setup and select PROGRAM (preset parameters) for phacoemulsification procedures in the SOVEREIGN™ COMPACT System memory.

- AMO DEFAULT Setups
  - Settings
  - Diathermy
  - I/A
  - Phaco
  - Vitrectomy

- STARTUP

- PROGRAM
  - Program SETTINGS
  - Program DIATHERMY
  - Program PHACO
  - Program I/A
  - Program VITRECTOMY
  - Program END CASE
  - SAVE OPTIONS Program
  - SAVE AS Program
  - SAVE after Operation

AMO DEFAULTS Setups

Before You Begin

Before creating new presets and programming your SOVEREIGN™ COMPACT System, you may want to consider the AMO Setup (called AMO DEFAULTS) that is already preset for you.

Figure 5.1
SETUPS

Global to Each Surgeon Program/Setup		
Parameter	**Available Settings**	**AMO DEFAULTS Settings**
Tap for Continuous Irrigation	On, Off	Off
Reflux Foot Switch	On, Off	On
Side Foot Switches	On, Off	On
Foot Pedal Feedback	On, Off	Off
Foot Pedal Threshold FP1	0 - 100%	10%
Foot Pedal Threshold FP2	FP1 - 100%	20%
Foot Pedal Threshold FP3	FP2 - 100%	60%
Sound Volume	0 (None) - 10 (Max)	3
Vacuum Audio Signal	On, Off	On

Figure 5.2
DIATHERMY

Parameter	**Available Settings**	**AMO DEFAULTS Settings**	
		D1	**D2**
Max Power	5 - 100%	50%	50%
Power Delivery Type	Linear, Burst, Panel	Linear	Burst

Figure 5.3
I/A

Parameter	**Available Settings**	**AMO DEFAULTS Settings**		
		I/A1	**I/A2**	**I/A3**
IV Pole Height	0 - 76 cm	70 cm	30 cm	75 cm
Max Vacuum	0 - 500 mmHg	500 mmHg	10 mmHg	400 mmHg
Max Aspiration Rate	0 - 50 cc/min	32 cc/min	6 cc/min	50 cc/min
Vacuum Mode	Linear, Panel	Linear	Linear	Linear
Flow Mode	Linear, Panel	Panel	Panel	Panel

Figure 5.4 - PHACO

Parameter	Available Settings	AMO DEFAULTS Settings			
		Phaco 1	**Phaco 2**	**Phaco 3**	**Phaco 4**
IV Pole Height	0 - 76 cm	65 cm	75 cm	70 cm	75 cm
Max Vacuum	0 - 500 mmHg	40 mmHg	250 mmHg	180 mmHg	300 mmHg
Max Aspiration Rate	10 - 50 cc/min	20 cc/min	28 cc/min	28 cc/min	32 cc/min
Vacuum Mode	Linear, Panel*	Linear	Linear	Linear	Linear
Flow Mode	Linear, Panel*	Panel	Panel	Panel	Panel
Occlusion Threshold	-	40 mmHg	125 mmHg	60 mmHg	150 mmHg
Occlusion Mode	On, Off	Off	On	On	On
Max Power	0 - 100%	60%	40%	20%	50%
Power Delivery Type	Linear, Panel	Linear	Linear	Linear	Linear
Power Delivery Mode	• Continuous • Short Pulse • Long Pulse • Low Power Pulse • High Power Pulse • Single Burst • Multi-Burst • Continuous Burst • Continuous WHITESTAR™ ** • Pulse WHITESTAR™ **	Continuous	Continuous	Continuous	Continuous
Short Pulse Rate	1 - 14 pps	6 pps	6 pps	6 pps	6 pps
Long Pulse Rate	1 - 6 pps	6 pps	6 pps	6 pps	6 pps
WHITESTAR™ Technology	C/F, B/D, C/B, C/D D/B, C/L, D/L, C/I	C/F	C/F	C/F	C/F
Max Aspiration Rate Occluded***	10 - 50 cc/min	20 cc/min	28 cc/min	16 cc/min	24 cc/min
Max Power Occluded***	0 - 100%	60%	40%	20%	50%
Power Delivery Type Occluded***	Linear, Panel	Linear	Linear	Linear	Linear
Power Delivery Mode Occluded ***	• Continuous • Short Pulse • Long Pulse • Low Power Pulse • High Power Pulse • Single Burst • Multi-Burst • Continuous Burst • Continuous WHITESTAR™ ** • Pulse WHITESTAR™ **	Long Pulse	Long Pulse	Long Pulse	Continuous

* Cannot have Vacuum Mode and Flow Mode "linear" at the same time.
** Optional enhancement
*** Appears only when occlusion mode is activated

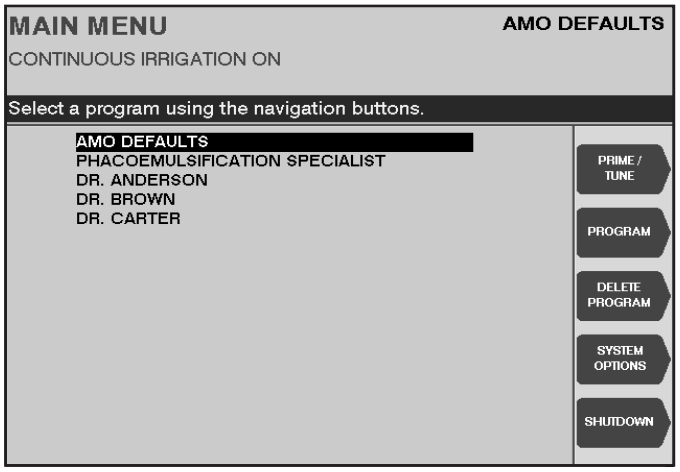
Figure 5.5 - VITRECTOMY

Customized to Each Surgeon Program/Setup

Parameter	Available Settings	AMO DEFAULTS Settings
IV Pole Height	0 - 76 cm	30 cm
Max Vacuum	0 - 500 mmHg	175 mmHg
Max Aspiration Rate	0 - 50 cc/min	20 cc/min
Cut Rate	100 - 600 cpm	450 cpm
Foot Pedal Mode	ICA, IAC, Side Vit	ICA

Startup

After you have turned on the SOVEREIGN™ COMPACT System, the machine will perform a series of Start Up Tests and the MAIN MENU will appear.



Program

After the Start Up tests are complete, the Main MENU appears. You are then ready to proceed to PROGRAM. On successful start up, the MAIN MENU screen displays the available programs for selection. A PROGRAM (or Surgeon Name) is simply a set of pre-established operating parameters for each operating mode. The SOVEREIGN™ COMPACT allows you to program up to 16 customized surgeon setups (programs).

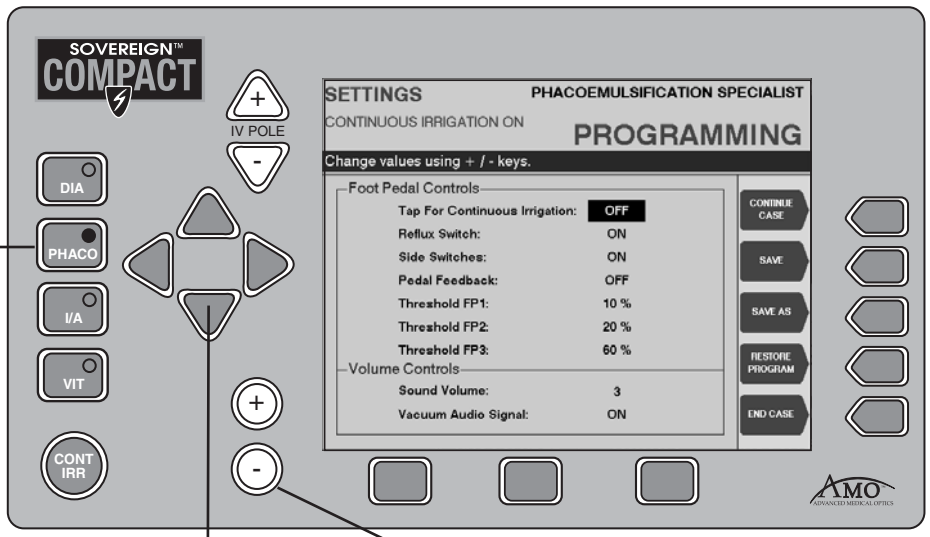
From the MAIN MENU you may:

- Create a new PROGRAM based on the values of a selected program
- Edit an existing PROGRAM (by selecting the PROGRAM, then changing settings)
- Delete a PROGRAM

If it is the first time the machine has been used, AMO DEFAULTS is the only PROGRAM that will appear on the screen.The first PROGRAM that you create will use the AMO DEFAULTS settings as a starting point, and then you may modify them and SAVE AS a specific program or surgeon name. The system will not allow you to overwrite the AMO DEFAULTS by pressing SAVE.

Program SETTINGS

1. From the MAIN MENU, press the PROGRAM softkey. The PROGRAM highlighted on the MAIN MENU will be used.
2. The SETTINGS screen will appear with current settings.Using the navigation buttons (1), select the parameter(s) to be changed, and then use the value adjust buttons (2) to change the value.



MODE
Select Buttons
- DIA
- PHACO
- I/A
- VIT

1 Use Navigation buttons to select the desired parameter.

2 Use Value Adjust buttons to change a parameter value.

SETTINGS - allows for preselection of operational features and options pertinent to general operation, the foot pedal and audio.

TAP FOR CONTINUOUS IRRIGATION - This is a feature that allows surgeon control of Continuous Irrigation. When ON, the surgeon may quickly tap the foot pedal from FP0 (foot position 0) to FP1 (foot position 1) to toggle Continuous Irrigation ON/OFF. This is a program specific feature.

REFLUX SWITCH - This allows reflux on the top foot pedal switch to be ON or OFF. When ON, reflux occurs while the top switch is depressed. When OFF, the top switch has no function. This is a program specific feature.

SIDE SWITCHES - The side switches provide surgeon control of sub-mode change. Specifically, when ON, the right side switch selects the next MMP (example: Phaco 2 to Phaco 3) and the left side switch selects the next lower MMP (example: Phaco 4 to Phaco 3). Both switches are one direction only. When OFF, the side switches have no MMP functionality. This is a program specific feature.

Program SETTINGS (cont.)

PEDAL FEEDBACK - When ON, provides tactile feedback that allows the surgeon to feel when the foot pedal transitions between the different positions. This is a program specific feature.

THRESHOLD FP1, FP2 and FP3 - Allows the surgeon to program where the foot pedal will transition from Position 0 to Positions 1, 2, and 3. The percentage figure is based on 100% of total foot pedal travel. (Halfway down = 50% travel.) This is a program specific feature.

SOUND VOLUMES - Adjusts system volume on a scale of 0 (off) to 10 (loudest). The diathermy tone volume is not adjustable as a certain minimum volume is required for standards conformity. The vacuum signal has an independent volume control. This is a system wide feature.

VACUUM AUDIO SIGNAL - When ON, provides a rising tone proportional to vacuum level to assist surgeon in determining vacuum level acheived. This is a program specific feature.

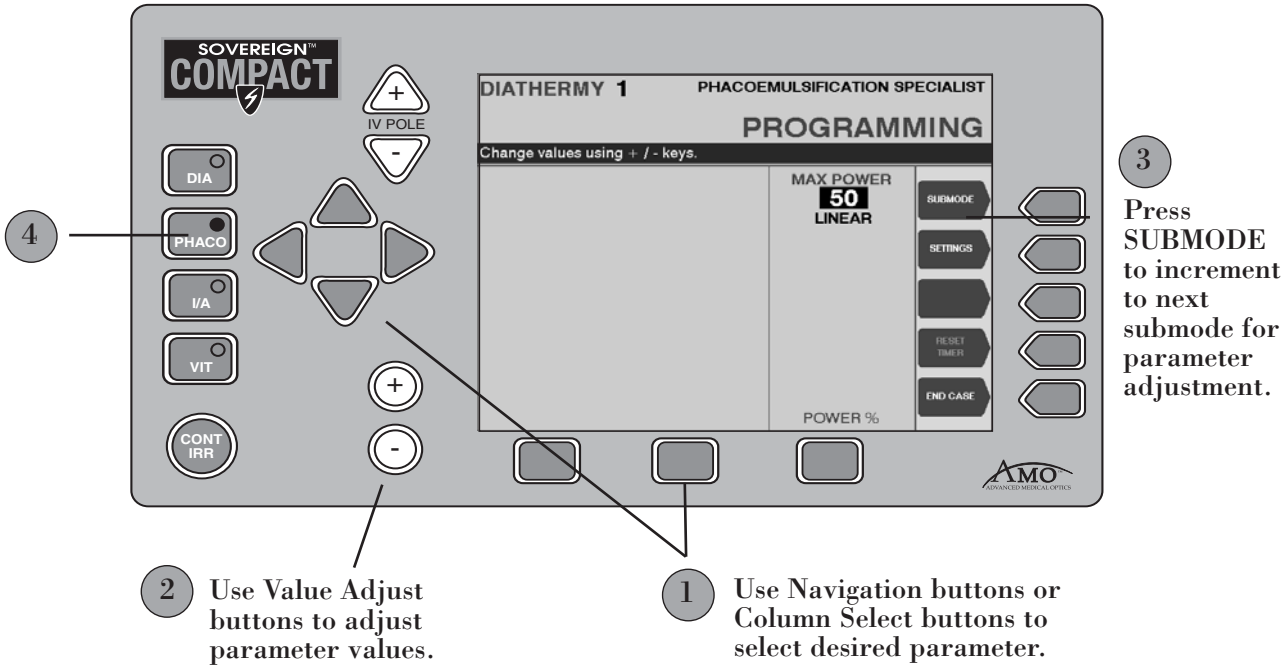
3. After all desired SETTINGS values have been changed, press the DIATHERMY mode select button to program DIATHERMY.

Note: If you entered SETTINGS while in an OPERATING mode, pressing CONTINUE CASE will redisplay the OPERATE mode that you were in when you selected SETTINGS.

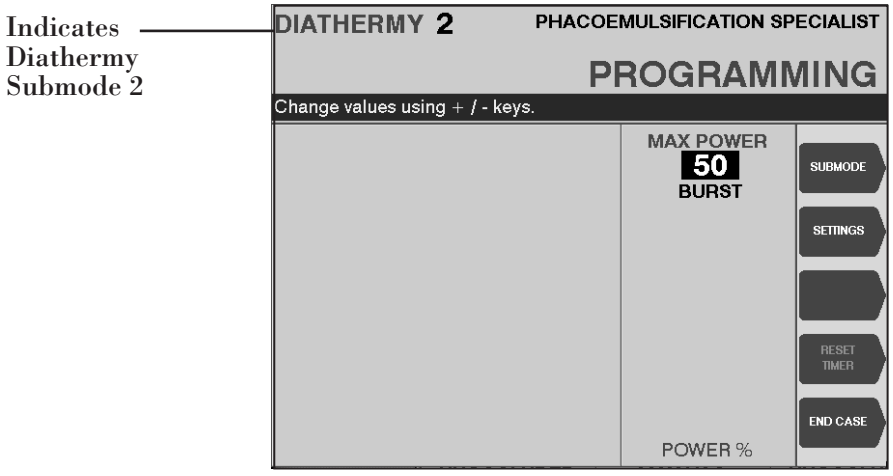
Note: All programming of surgical modes (except diathermy) PRIOR to a Prime/Tune MUST be entered via this SETTINGS screen. If a prime has not been completed, and IV pole programming is desired, use the IV pole and key to raise pole to its maximum height, calibrating pole.

Program DIATHERMY

1. From the DIATHERMY program screen, use the navigation buttons and column select buttons to select the desired DIATHERMY 1 values to be changed.
2. Use the value adjust buttons to adjust the value(s).



3. After the DIATHERMY 1 values are set, press SUBMODE softkey to program DIATHERMY 2. Select and change the parameter values for the submode.

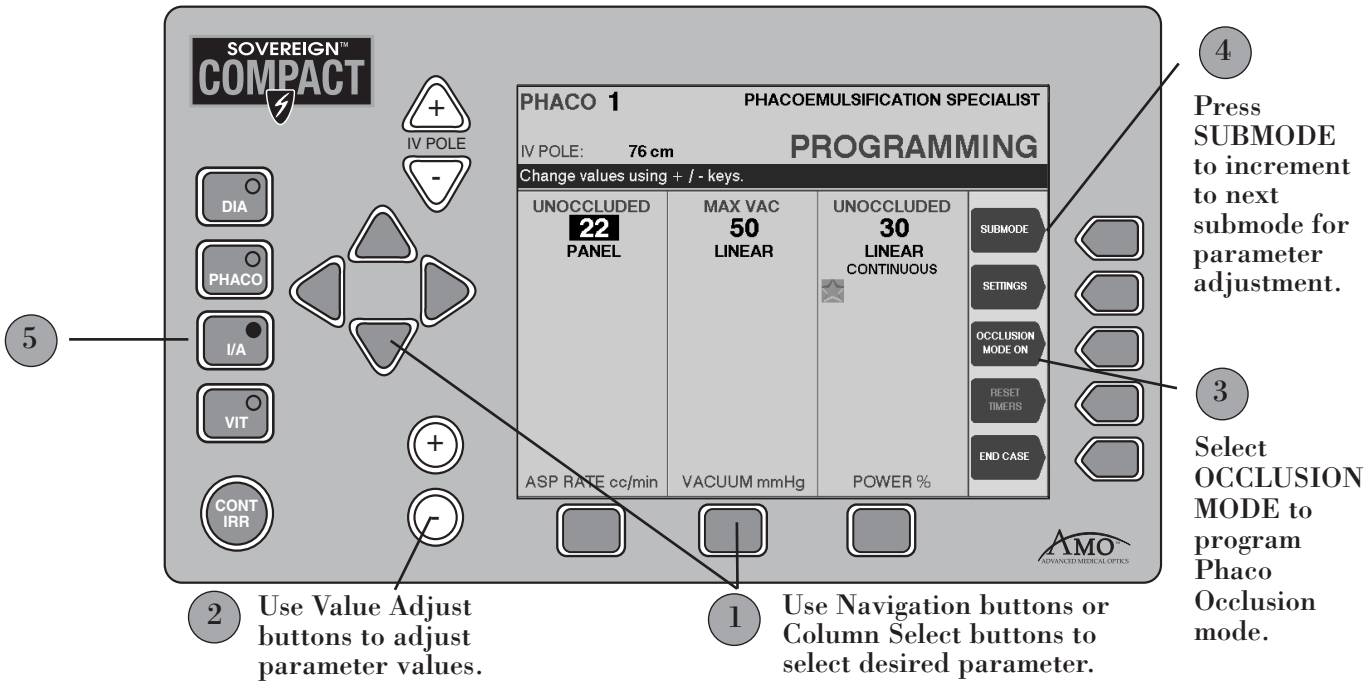


4. After the submode parameters are set, press the PHACO Mode select button to proceed with programming of the next mode, PHACO, or, END CASE if no other changes are needed.

Program PHACO

Note: If IV POLE display indicates "NOT CAL" and programming of IV POLE heights is desired, raise pole manually to maximum height to calibrate pole and display "76 cm".

1. From the PHACO PROGRAM screen, use the navigation buttons and column select buttons to move to the parameters to be selected.
2. Use the value adjust buttons to adjust the values for PHACO 1.
3. If Occlusion Mode is desired, select OCCLUSION MODE ON soft key.

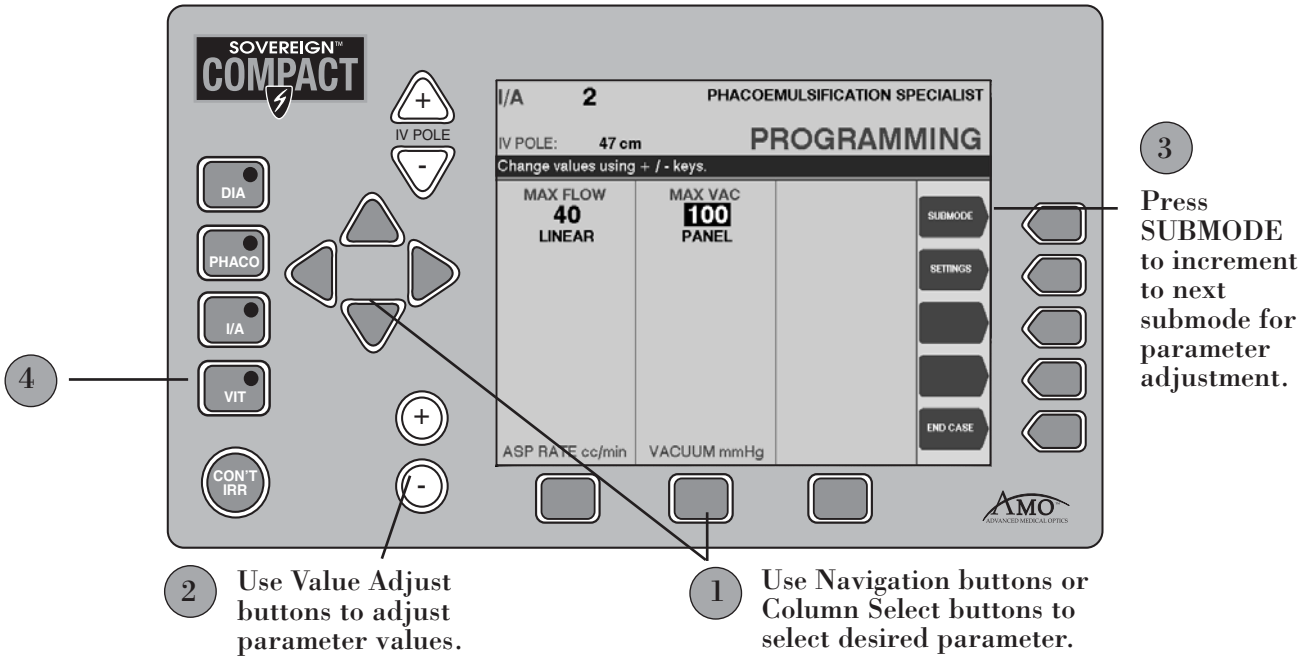


4. After PHACO 1 parameters are set for both OCCLUSION MODE and UNOCCLUDED MODE, press SUBMODE softkey to proceed to the next submode, PHACO 2. Repeat steps above for parameter adjustment of PHACO 2, PHACO 3, and PHACO 4 submodes, OCCLUDED and UNOCCLUDED.
5. After all 4 PHACO submodes are programmed, press the I/A MODE select button to proceed with programming the I/A MODE, or, END CASE if no other changes are needed.

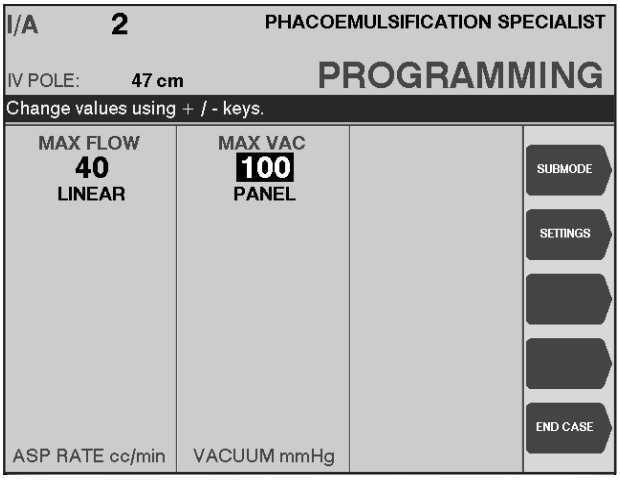
Program I/A

Note: If IV POLE display indicates “NOT CAL” and programming of IV POLE heights is desired, raise pole manually to maximum height to calibrate pole and display “76 cm”.

1. From the I/A PROGRAM screen, use the navigation buttons and column select buttons to move to the parameters to be selected.
2. Use the value adjust buttons to adjust the values for I/A.



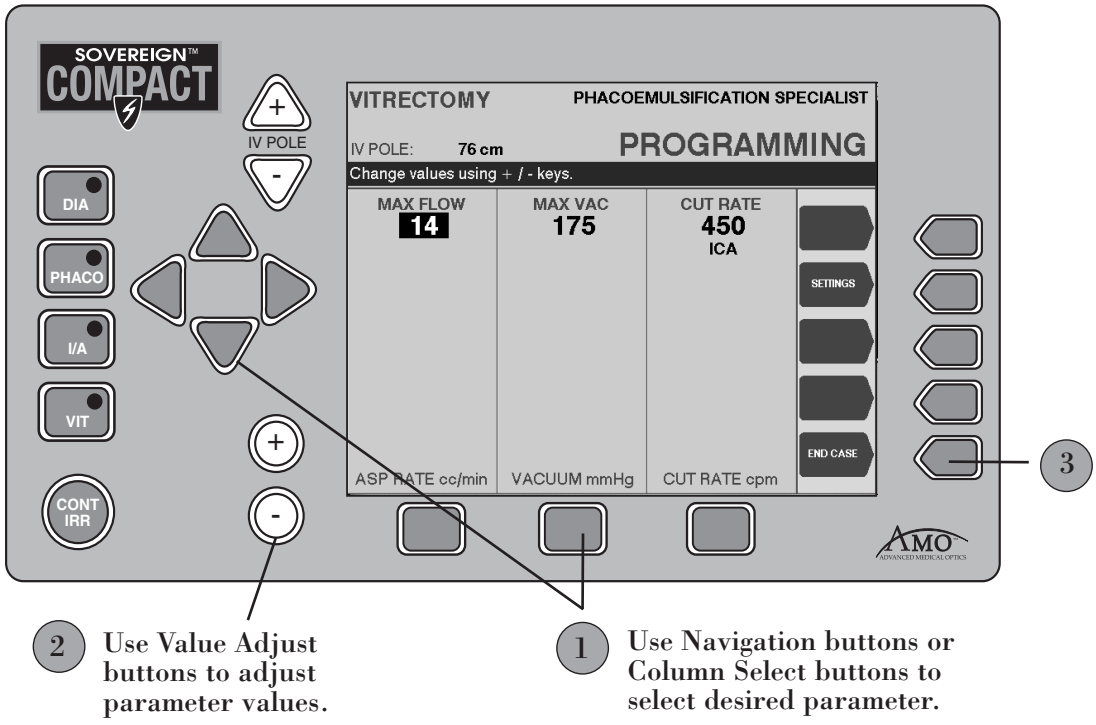
3. Press the SUBMODE softkey to proceed to the next two submodes, I/A 2 and I/A 3. Repeat steps above for parameter adjustment of the I/A submodes.



4. After all MODES and SUBMODES are programmed, press the VIT MODE select button to proceed with programming VIT MODE. or, END CASE if no other changes are needed.

Program VITRECTOMY

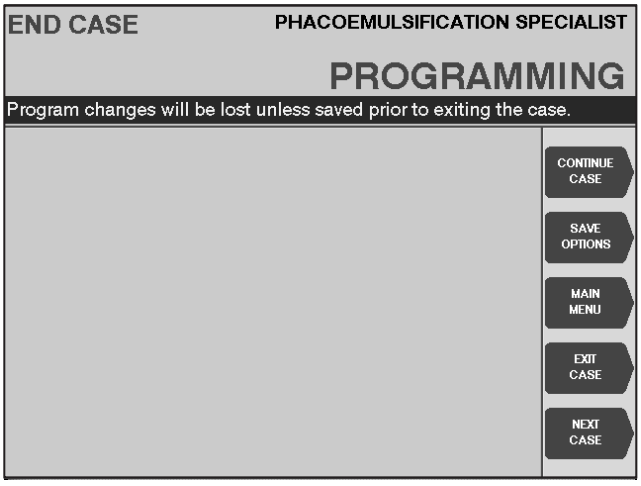
1. From the VIT PROGRAM screen, use the navigation buttons and column select buttons to move to the parameters to be selected.
2. Use the value adjust buttons to adjust the values for VIT.



3. After the VIT MODE is programmed, press END CASE. The END CASE screen will appear.

Program END CASE

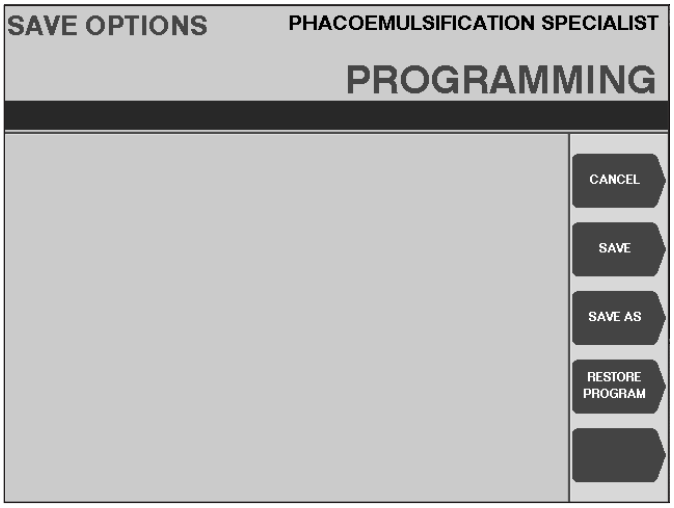
The END CASE Function is available from any programming or surgical mode. It allows for termination of the programming session or surgical case. If changes were made to the program settings, an opportunity will be given to save the settings.



SAVE OPTIONS Program

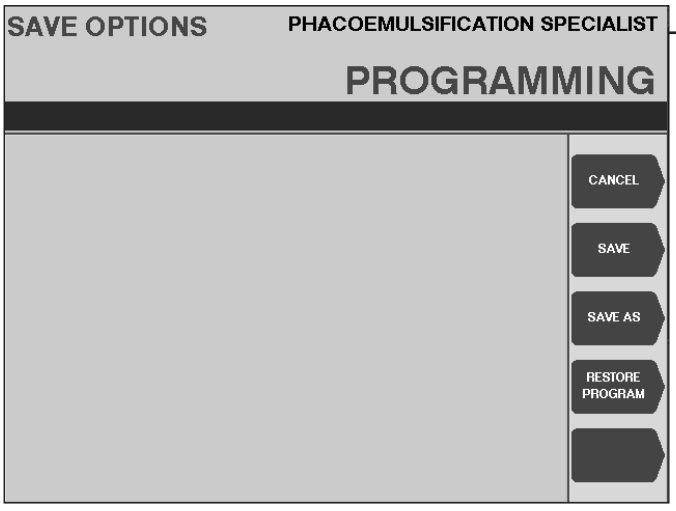
After all settings have been selected for the four operating Modes, you have the following SAVE OPTIONS:

- SAVE the program changes to the PROGRAM name selected at the start of programming.
- SAVE AS, which saves the program changes (made to an existing program) to a new program/surgeon name.
- RESTORE PROGRAM, erases the program changes and resets the values back to their last saved values.
- CANCEL, returns to END CASE without saving or restoring.



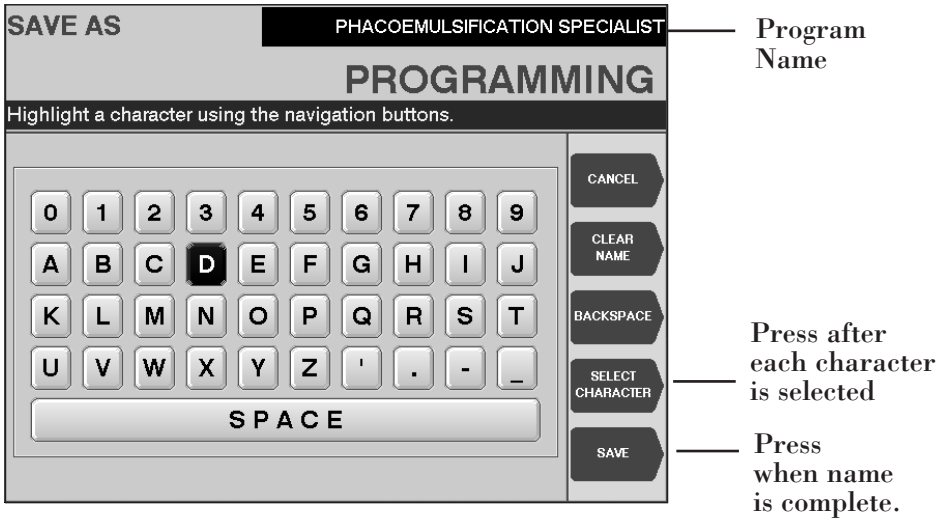
SAVE AS

1. From the SAVE OPTIONS screen, press the softkey for SAVE AS. The following screen will appear.

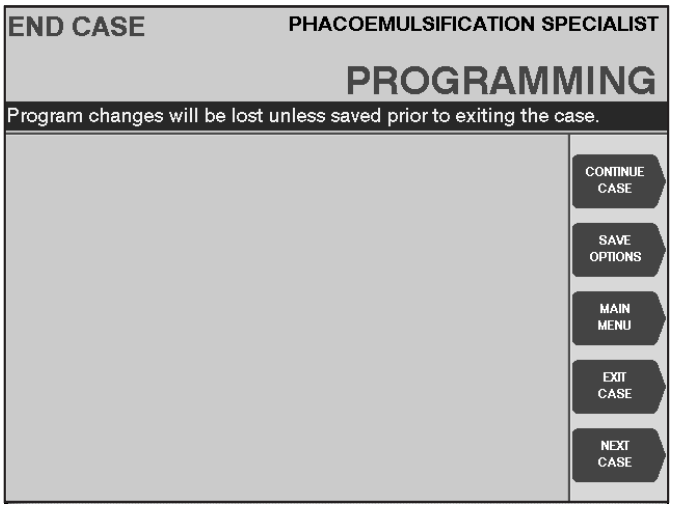


SAVE AS (Cont.)

2. Press CLEAR NAME to create clean field for new program name.
3. Using the navigation keys, select the characters to spell the program name, pressing SELECT CHARACTER for each chosen character. As you choose the characters, the name will appear in the upper right of the SAVE AS screen.


SAVE AS
PHACOEMULSIFICATION SPECIALIST
PROGRAMMING
Highlight a character using the navigation buttons.
0 1 2 3 4 5 6 7 8 9
A B C D E F G H I J
K L M N O P Q R S T
U V W X Y Z ' . - _
SPACE
CANCEL
CLEAR NAME
BACKSPACE
SELECT CHARACTER
SAVE
Program Name
Press after each character is selected
Press when name is complete.

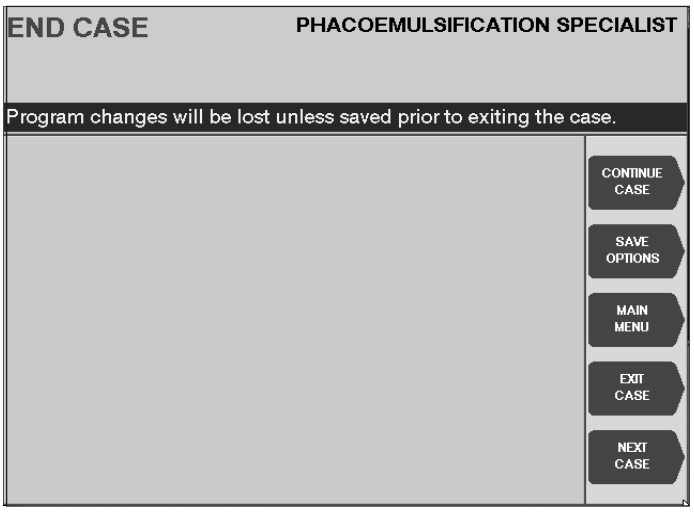
4. Press SAVE when the name has been successfully typed in. The SETTINGS or END CASE screen will be displayed, depending on which screen SAVE AS was accessed through.



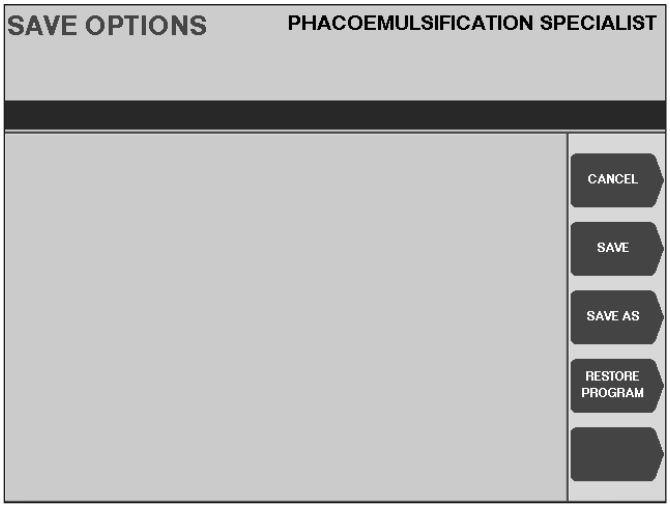
SAVE PROGRAM After Operation

At the end of a surgical case, you have the option of saving the program settings used for that case.

1. Press END CASE from any of the Operating screens. The END CASE screen will appear.



2. Press SAVE OPTIONS. The SAVE OPTIONS screen will display:
   - CANCEL will redisplay the END CASE screen and neither save nor restore the program values.
   - SAVE the program modifications to the current program name. END CASE will then be redisplayed.
   - SAVE AS, save the program modifications to a new program name (as described previously in SAVE AS). END CASE will then be redisplayed.
   - RESTORE PROGRAM will not save any program changes made during the case and restores the original programmed values. END CASE will then be redisplayed.



6 OPERATING MODES

This section provides descriptions and operational instructions for:

- Setup
- Continuous Irrigation
- Prime/Tune
- Verify Irrigation/Aspiration Balance
- Diathermy
- Phacoemulsification
- Irrigation/Aspiration
- Vitrectomy
- End Case

Setup

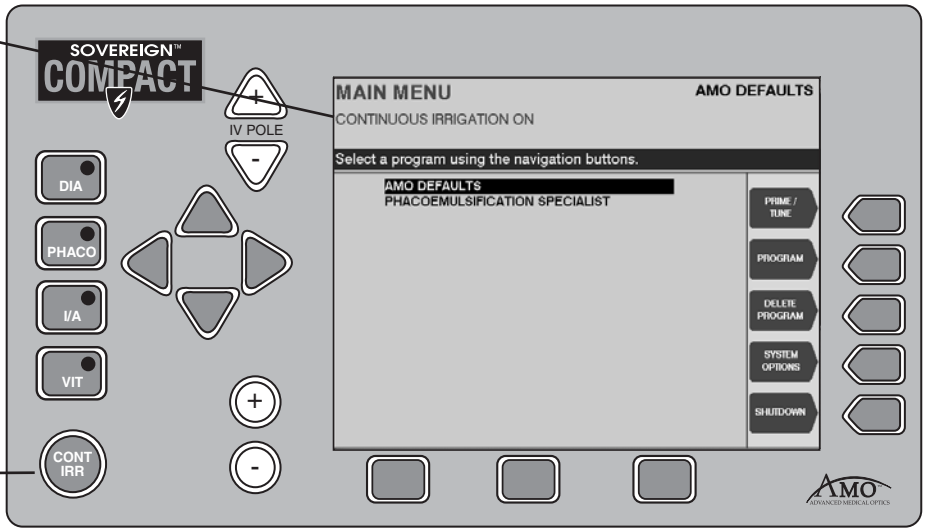
After the I/A tubing manifold has been correctly installed, the handpieces have been properly connected, and a PROGRAM has been setup (or you choose to operate with the AMO Default program), you are ready to proceed with OPERATION.

Continuous Irrigation

Continuous Irrigation is designed for collection of balanced salt solution for use during the case. This function opens the irrigation valve for fluid collection independent of the foot pedal or prime cycle.

Press the CONT IRR button to open the valve and start the flow of irrigation fluid. Press CONT IRR again to close the valve and stop the flow of fluid.

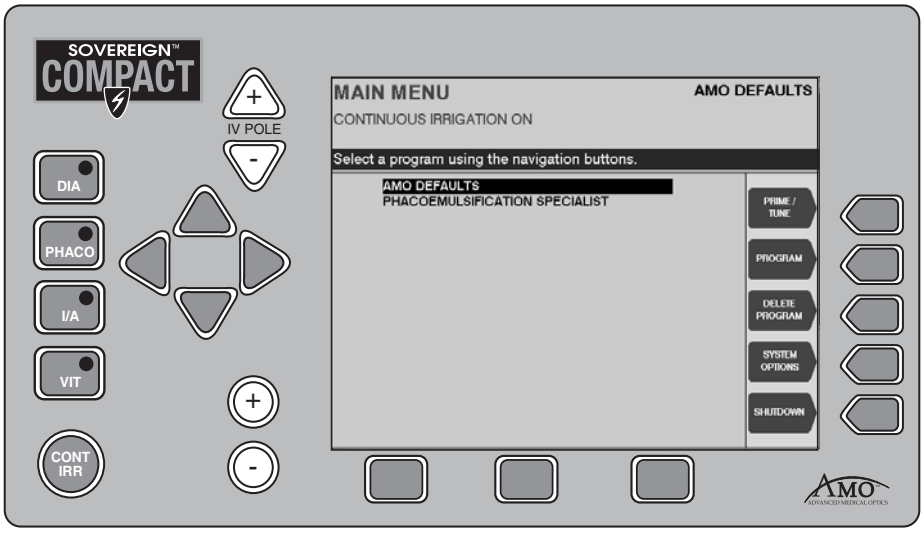
Indicates CONT IRR is on.



CONT IRR button turns irrigation off and on.

Select Program

From the MAIN MENU, use the navigation keys to select the desired PROGRAM.



PRIME/TUNE
- ***Prime/Tune***
- ***I/A Prime***
- ***Phaco Tune***
- ***Bypass Prime***

PRIME/TUNE is required before Phaco is performed to fill the I/A tubing with fluid, perform vacuum checking and to test and characterize the phaco handpiece. Prime and Tune are required:

- before each procedure
- anytime the handpiece is reconnected
- after Next Case has been pressed and before the next case is started

I/A PRIME is designed for a procedure not requiring a phaco handpiece.

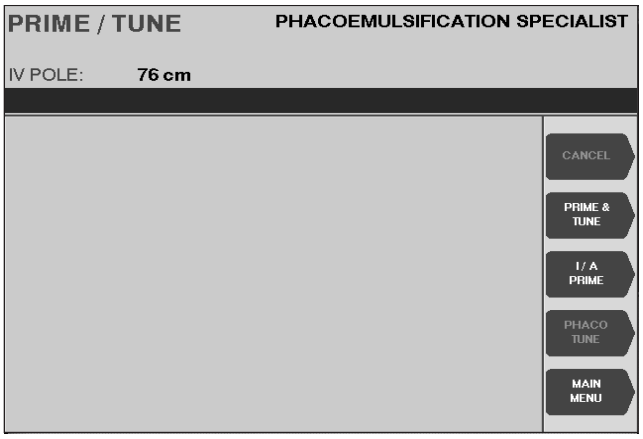
PHACO TUNE is designed for quick tuning of the phaco handpiece with an established I/A tubing set. It may be used if an ultrasonic phaco tip is replaced during a procedure.

BYPASS PRIME shortens the overall fluidics prime sequence and reduces the overall time to prime the SOVEREIGN™ COMPACT. It should be used only with an established I/A tubing set or priming errors may occur.

All of the PRIME/TUNE routines are selected from the PRIME/TUNE MENU.

Note: Diathermy may be performed during Prime ***(see p. 6-7).***

NOTE: PRIME/TUNE is a combination of I/A PRIME followed by PHACO TUNE. The SOVEREIGN™ COMPACT System tracks sucessful completion of each independently. Therefore, in the event a re-tune is required (new tip, failed tune, etc.), only the PHACO TUNE need be selected and run.

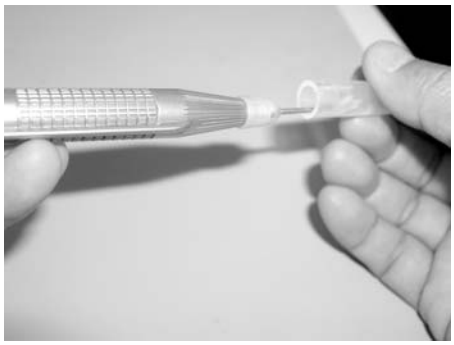


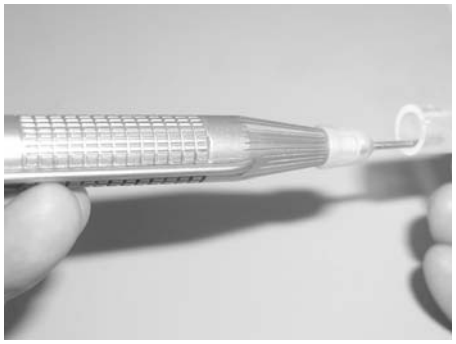
CAUTION

THE PHACO AND VITRECTOMY HANDPIECES SHOULD NEVER BE ACTIVATED WITH THEIR TIPS IN THE AIR. DOING SO WILL DRASTICALLY REDUCE THEIR USEFUL LIFE. IF POWER IS TO BE INTRODUCED TO THE PHACO OR VITRECTOMY HANDPIECES, THEIR TIPS SHOULD BE IN A TEST CHAMBER FILLED WITH IRRIGATING SOLUTION, IN A CONTAINER OF IRRIGATING SOLUTION OR IN THE PATIENT'S EYE.

PRIME/TUNE (Cont.)

Tips for Priming Handpiece



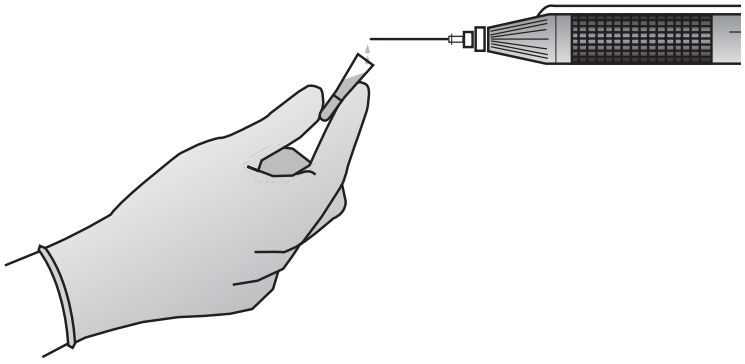


- Always fill the test chamber completely prior to running Prime/Tune Cycle.
- Do not lay the handpiece and empty test chamber down and have the machine fill the test chamber. This will allow air to collect in the test chamber and can produce an error.
- To collect balanced salt solution into the test chamber, a medicine cup or similar container, turn on CONT IRR, collect the fluid, turn off CONT IRR, then perform a full Phaco Prime Tune.
- The PRIME/TUNE screen will indicate the progress of the priming process.

1. Using the CONT IRR function, fill the test chamber with fluid, eliminating all air and place the test chamber over the handpiece tip and the sleeve hub. See Figure 6.1.

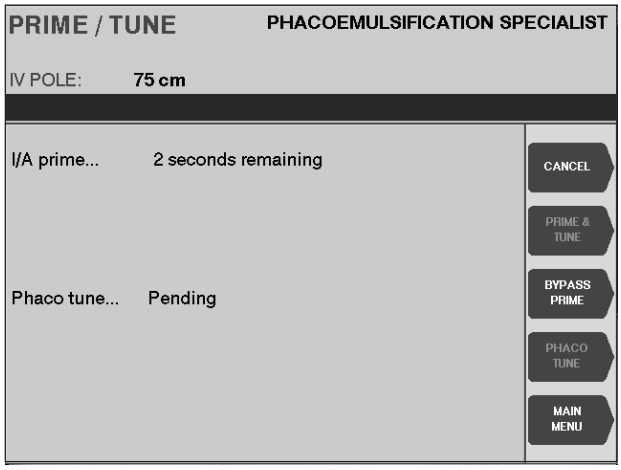
Figure 6.1

Prime Handpiece and Fill Test Chamber



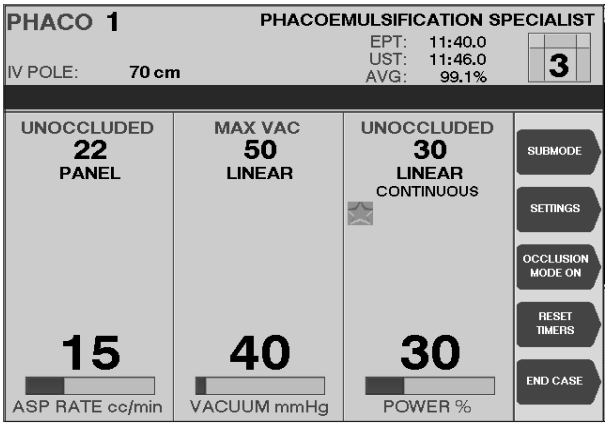
Prime/Tune (Cont.)

2. Press the PRIME TUNE, I/A PRIME, or PHACO TUNE softkeys depending on the procedure you intend to do. This will start the PRIME and TUNE sequences.
3. The I/V pole will travel to its maximum setting (assure low ceilings or satellite systems do not impede travel to the maximum setting). Watch for the fluid as it fills the drip chamber and travels toward the handpiece, through full test chamber.



4. The PRIME/TUNE screen will indicate the progress of the priming and tuning process.
5. As the tubing lines are filled, the system software performs functional checks. These include monitoring for the presence of irrigation flow (bottle height) and leaks (via vacuum rise checks). If the phaco handpiece is plugged in and PRIME/TUNE or PHACO TUNE were selected, the system will automatically include a handpiece tuning test at the end of the prime cycle. At the end of the priming sequence, the SOVEREIGN™ COMPACT System plays an audible sound to indicate that priming is complete and a message appears on the screen. At the end of the phaco tuning test, the SOVEREIGN™ COMPACT System plays another audible alert tone and a message appears on the screen.
6. To discontinue PRIME or TUNE during the process, simply select CANCEL from the PRIME/TUNE screen.

7. When PRIME and TUNE are complete, system automatically proceeds to the PHACO 1 operating mode. It is important that you verify the I/A balance as described below, prior to operating.



IMPORTANT

After the Priming Prime/Tune procedure is completed, it is strongly recommended that you complete the following steps to verify the irrigation/ aspiration balance at the programmed settings to be used in surgery.

Verify Irrigation/ Aspiration Balance

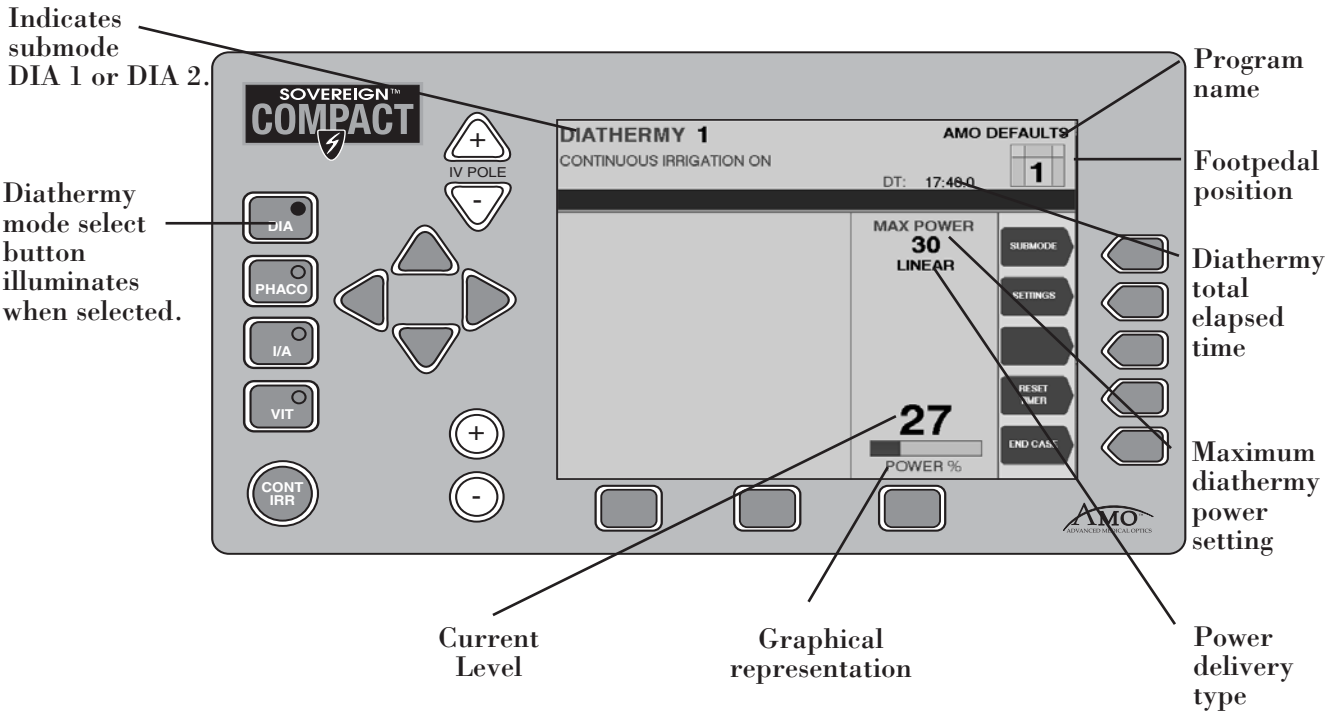
1. PHACO 1 mode will be displayed on the front panel at the completion of PRIME/TUNE. Hold handpiece at approximate patient eye level.
2. Press and hold the foot pedal in position 3. Occlude the aspiration line just below the ultrasonic handpiece. The actual vacuum level should rise to the preset level.
3. Release the occlusion and watch the test chamber to make sure that it does not collapse. A slight shallowing of the chamber is normal.
4. To test irrigation, pinch the irrigation tubing at the handpiece and watch for the test chamber to collapse. Release the irrigation line and the test chamber should refill.
5. Select RESET TIMERS on the PHACO screen to delete any accumulated phaco time.

Diathermy

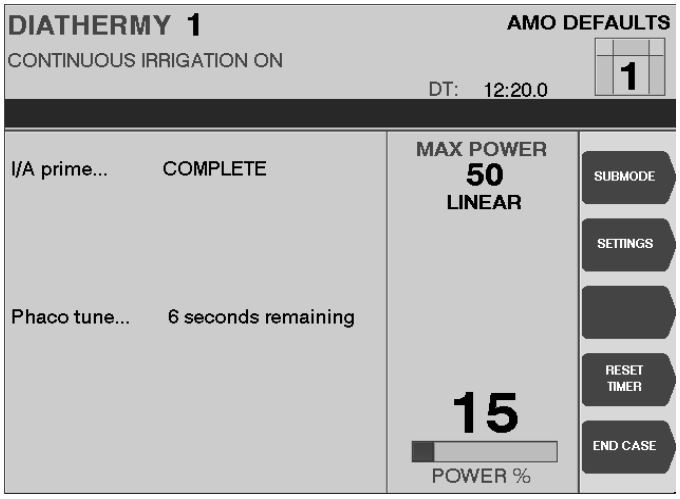
During Prime

While the system is priming, you may select the Diathermy (DIA) mode (a function which does not require irrigation and aspiration flow) and perform Diathermy procedures.

To select Diathermy, press the DIA MODE select button and then use SUBMODE softkey to select DIA 1 or DIA 2 (one of the two Diathermy submodes).



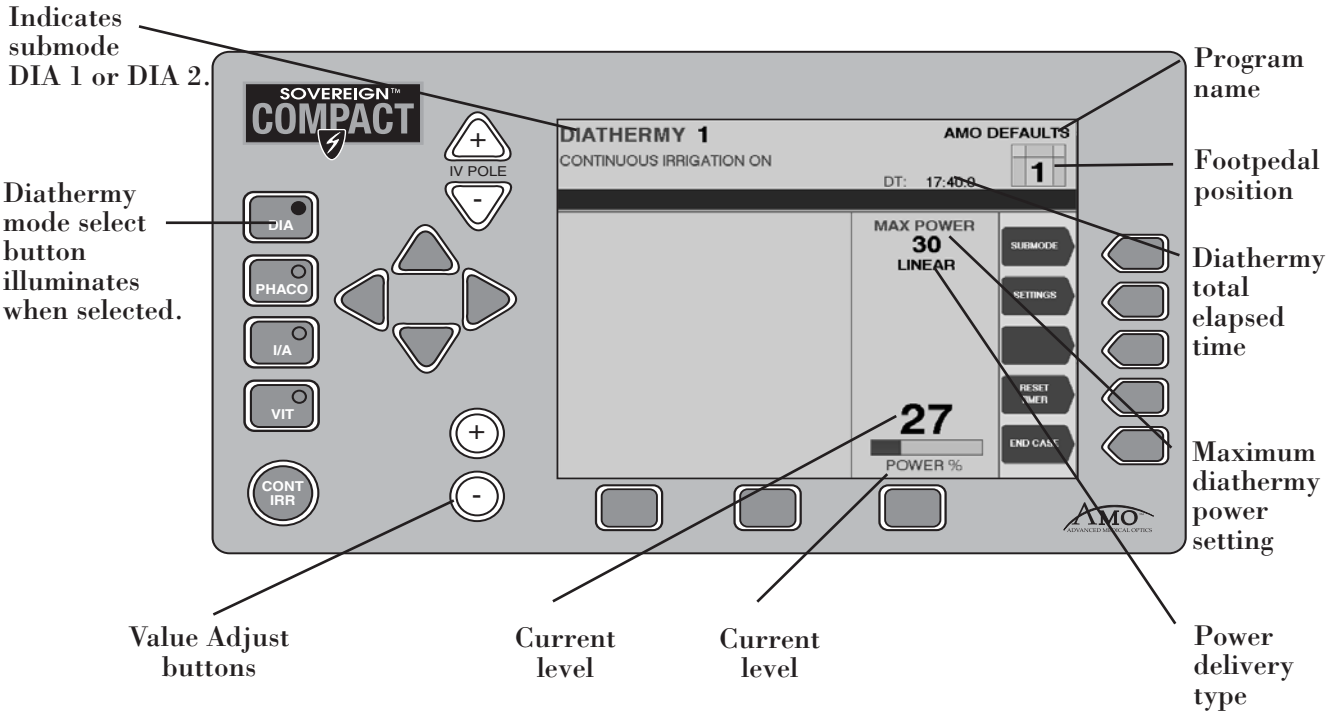
If Diathermy is selected during Prime, the screen indicates the PRIME TUNE status and any messages associated with the prime and/or tune.



Diathermy (Cont.)

Using Diathermy

The SOVEREIGN™ COMPACT System provides power for bipolar coagulation, or diathermy. The amount of diathermy power is displayed on the Diathermy screen. It can be changed by selecting the power setting and using the +/- keys. The Diathermy power may be delivered as PANEL, LINEAR or BURST.



PANEL - Diathermy power is delivered consistently at the power level (%) selected and indicated on the screen as MAX POWER.

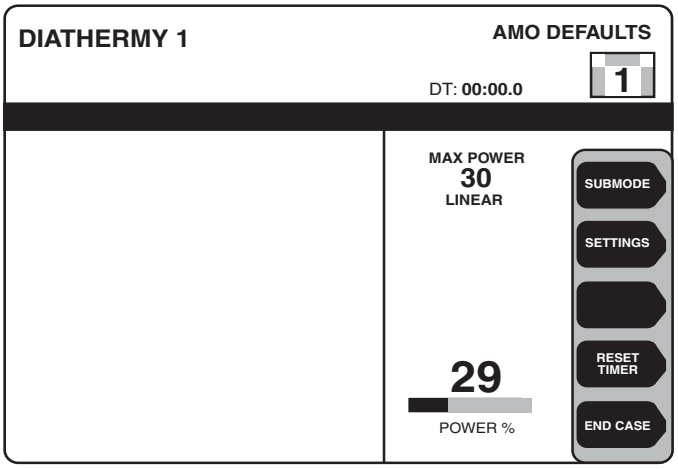
LINEAR - Diathermy power is delivered from 5% to the maximum selected value (MAX Power) as the foot pedal is pressed.

BURST - Diathermy is delivered as a single 150 msec. pulse as the footpedal is pressed.

Diathermy (Cont.)

Using Diathemy (Cont.)

1. Press DIATHERMY MODE and use the SUBMODE softkey to select DIA 1 or DIA 2.



2. Press the foot pedal to activate Diathermy. The display will indicate the actual power being delivered and the cumulative foot pedal time that Diathermy has been used during the procedure.

Phacoemulsification

4 Submodes

The purpose of phacoemulsification is to emulsify the lens material. The phacoemulsification (phaco) handpiece provides ultrasonic energy, irrigation and aspiration simultaneously so that the lens material is extracted as it is emulsified.

IMPORTANT

Before phacoemulsification, it is strongly recommended that you complete the steps outlined on page 6-6 to verify the Irrigation/Aspiration balance.

Phacoemulsification (Cont.) The Phaco mode has three sets of adjustable operating parameters for each of the four Phaco Submodes:

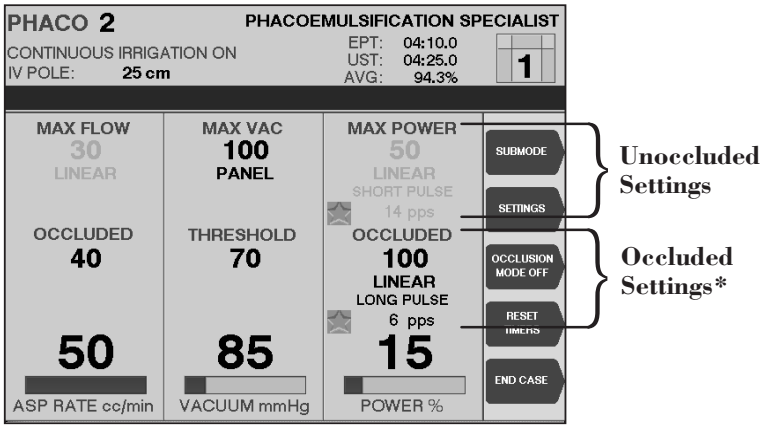
Operating Parameters

Parameter	Adjustments	Settings Range/Options
I/V POLE HEIGHT		0 to 76 cm
ASP RATE	Occluded Rate	10 to 50 cc/min
	Unoccluded Rate Linear or Panel	10 to 50 cc/min
VACUUM	Maximum Vac Threshold Linear or Panel	0 to 500 mmHg 0 to Max Vac
POWER	• Unoccluded Power Level Max Power	0 to 100%
	Power Delivery Mode Linear or Panel	Continuous Short Pulse Long Pulse Low Power Pulse High Power Pulse Continuous WHITESTAR™* Technology Pulse WHITESTAR™* Technology
	Power Delivery Mode Panel	Single Burst Multi-Burst Continuous Burst
	Delivery Type Pulse Rate	Linear or Panel (see above) Short Pulse: 1-14 pps Long Pulse: 1-6 pps Pulse WHITESTAR™* Technology: 1-5 pps
	WHITESTAR™ Technology*	C/F, B/D, C/B, C/D, D/B, C/L, D/L, C/I
	• Occluded Power Level Max Power	0 to 100%
	Power Delivery Mode Linear or Panel	Continuous Short Pulse Long Pulse Low Power Pulse High Power Pulse Continuous WHITESTAR™* Technology Pulse WHITESTAR™* Technology
	Power Delivery Mode Panel	Single Burst Multi-Burst Continuous Burst
	Delivery Type Pulse Rate	Linear of Panel (see above) Short Pulse: 1-14 pps Long Pulse: 1-6 pps Pulse WHITESTAR™* Technology: 1-5 pps
	WHITESTAR™ Technology*	C/F, B/D, C/B, C/D, D/B, C/L, D/L, C/I

* Optional enhancement; check with your local AMO representative for availability

Phacoemulsification (Cont.)

* The Occluded Settings are displayed only if the occlusion mode is On. Also, Occluded Settings are dimmed during Operation until an occlusion occurs, then Unoccluded Settings are dimmed.



Aspiration Rate

ASP RATE (aspiration flow) is the speed at which material is evacuated from the eye through the aspiration line. It is adjustable from 10 to 50 cc/minute in 2 cc increments, and may be PANEL or LINEAR. The flow rate reduces as the vacuum approaches the maximum level. The SOVEREIGN™ COMPACT System allows you to establish separate ASP RATE (aspiration flow) settings for OCCLUDED and UNOCCLUDED. OCCLUDED refers to occlusion of the phaco tip, and allows the setting to be made without limiting the choice of aspiration flow rate through an UNOCCLUDED tip.

PANEL flow rate provides continuous evacuation at the established maximum flow rate.

LINEAR flow increases from 10 cc/min to the maximum selected flow rate (up to 50 cc/min) as the foot pedal is pushed through position 2.

Vacuum

Maximum vacuum determines the maximum suction force (MAX VAC) exerted on the aspirated fluid in the aspiration line. To assure fluidic balance while in phacoemulsification, MAX VAC is adjustable from 0 to 500 mmHg in increments of 5, and is indicated on the screen display.

Vacuum builds when the aspiration port is blocked or occluded by tissue or other material. The aspiration system fluid vents when you release the foot pedal to position 0, and vacuum is also relieved in position 1 using pump rotation. This vacuum release gently releases material at the aspiration port, giving you full control should the tip accidentally grab capsule or iris. Likewise, the internal fluidic system allows you to maintain a desired vacuum level simply by holding the foot pedal at a constant position.

If occlusion mode is active, the vacuum THRESHOLD setting allows the surgeon to choose the vacuum level at which occluded settings take effect.

Phacoemulsification (Cont.)

Power

Phaco power is separately adjustable from 0 to 100% for both OCCLUDED and UNOCCLUDED phaco tips. The display screen indicates both the maximum power settings and the actual phaco power being delivered. The phaco power may be either LINEAR or PANEL.

Linear phaco power allows you to control the phaco power using the foot pedal much like an accelerator on an automobile. The phaco power setting is the maximum value. Using the foot pedal, the power will increase from 0% to the maximum preset level. When the foot pedal is fully pressed, the power level will be at its maximum preset level. The power increase is indicated by the power display bar.

There are ten (10) choices for delivery of phaco power:

- Continuous
- Short Pulse
- Long Pulse
- Low Power Pulse
- High Power Pulse
- Single Burst
- Multi Burst
- Continuous Burst
- Continuous WHITESTAR™ *
- Pulse WHITESTAR™*

* Optional enhancement; check with your local AMO representative for availability

Continuous phaco power provides you with continuous, uninterrupted phaco power to the handpiece and requires no pulse rate setting.

Pulse phaco power causes the power to be pulsed at predetermined intervals when the foot pedal is in position 3. Within the PULSE setting, the surgeon can also select:

- **Short Pulse** is available in linear or panel power. It generates pulses of ultrasonic power of 50 ms duration. The user may select from a range of 1- 14 pulses per second.
- **Long Pulse** is available in linear or panel power. It generates pulses of ultrasonic power of 150 ms duration. The user may select from a range of 1-6 pulses per second.

Power Pulse is a combination of long and short pulses.

- **Low Power Pulse** is available in linear or panel power. It initially generates short pulses of ultrasonic power in foot position 3. As the foot pedal is depressed further, the pulses become longer and eventually blend together to become continuous phaco power.
- **High Power Pulse** is available in linear or panel power. It initially generates continuous phaco power in foot position 3. As the foot pedal is depressed further, the phaco power becomes pulsed and eventually short pulses of phaco power are delivered.

Even though the phaco power is pulsed, the aspiration flow remains constant. There are a variety of situations where pulsed phaco power is helpful:

1. Pulsed power gives greater control of loose nuclear fragments, and thus decreases "chatter" within the eye.
2. At high ultrasound powers, there is less formation of cavitation bubbles with pulsed power than with continuous power.
3. Pulsed power gives greater control (like "slow motion") for removing the peripheral nucleus in one-handed phaco procedures performed within the capsule.

Phacoemulsification (Cont.)

Power (Cont.)

Burst phaco power delivers short bursts of ultrasound power when the foot pedal is in position 3. Each burst is at the preset power level (non-linear). There are three settings available with the Burst mode selection:

- **Single Burst** delivers a single burst of ultrasonic power of 110 ms duration when the footpedal is depressed into position 3. The surgeon must return to footpedal position 2, pause for approximately 1/2 second, and then depress it back into position 3 to obtain an additional burst of energy. Rapid transitions from position 0 to 3 or between positions 2 and 3 may occasionally result in a burst omission.
- **Multi-Burst** generates bursts of ultrasonic power of 80 ms duration, with additional bursts deployed beginning at approximately 1 burst per second when foot position 3 is first entered. As the foot pedal is depressed further, the frequency of bursts will increase, until they are delivered at the rate of 4 bursts/second at maximum foot pedal depression.
- **Continuous Burst** delivers an 80 ms ultrasonic burst duration. As the footpedal is depressed through position 3, the bursts will get closer and closer together. At maximum depression of foot position 3, the bursts will blend together, and the power becomes continuous (at the preset power level).

WHITESTAR™ Technology* describes an advanced power modality which delivers finely modulated pulses of energy interrupted by extremely brief cooling periods. It is available in linear or panel power.

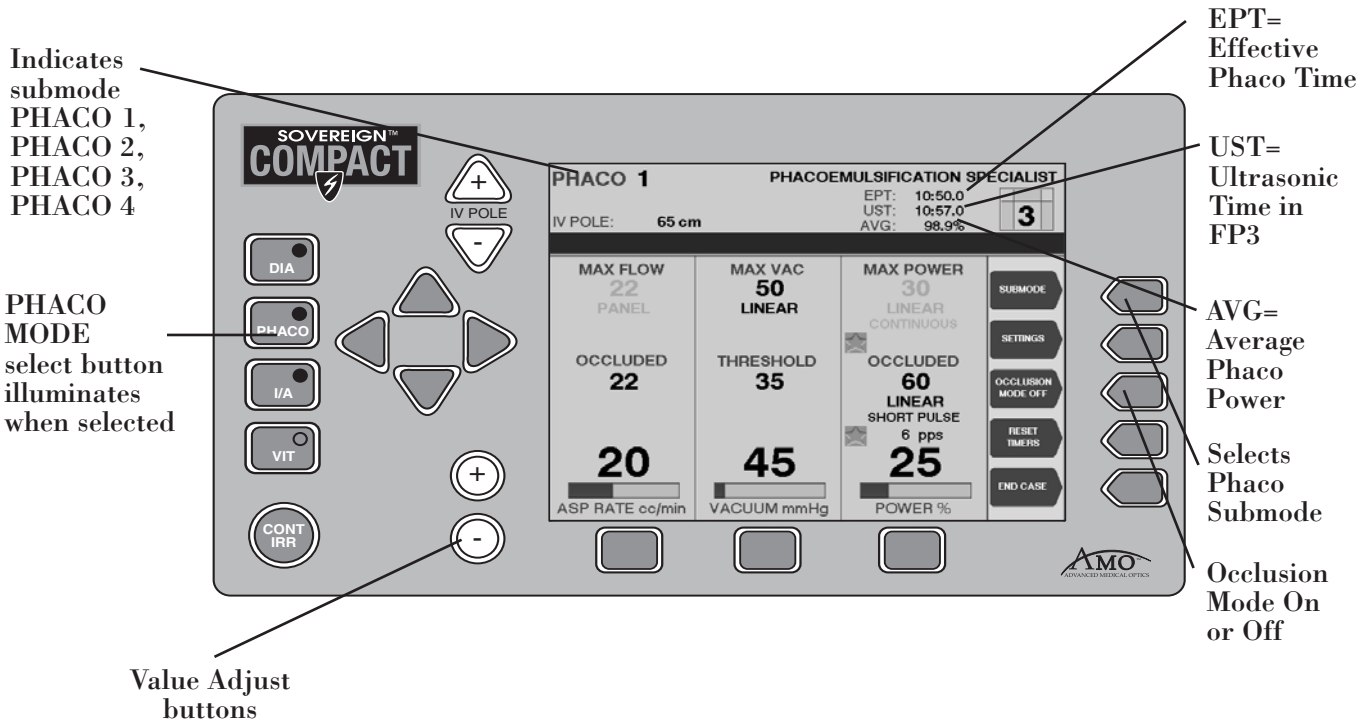
- **WHITESTAR™** tower mode is used in conjunction with continuous and pulse delivery. That is, the continuous or pulse power is delivered in fine pulses within each pulse or continuous output.
- Selection and adjustment of WHITESTAR™ Technology duty cycle is via alphabetic choices. The available settings are listed under operating parameters in this section.

* Optional enhancement; check with your local AMO representative for availability

Phacoemulsification (Cont.)

Using Phaco

1. Press the PHACO mode and use the SUBMODE softkey to select a SUBMODE. All settings for ASP RATE (aspiration flow), VACUUM and POWER will be displayed.
2. Press the foot pedal to activate phacoemulsification. The ASP RATE (aspiration flow),VACUUM and POWER graphical displays will indicate the associated levels throughout the procedure.



3. The timers in the upper right corner indicate Effective Phaco Time (EPT) and Ultrasonic Time in FP3 (UST). Effective Phaco Time is ultrasound time as a weighted total taking into account the amount of power being used:

   at 100% power: 1 sec. UST Time = 1 sec. EPT
   at 50% power: 1 sec. UST Time = .5 sec. EPT
   AVG (Average phaco power) is defined as EPT/UST.

Irrigation/Aspiration

3 Sub-Modes

Aspiration flow is necessary to remove the emulsified cataract material from the eye. An irrigation supply is necessary to replace fluid removed by aspiration of cortical material and fluid lost to leakage from the incision. This fluid balance maintains the anterior chamber during surgery.

Irrigation operates on a gravity flow principle. The flow rate of the irrigation solution through the irrigation sleeve on the phaco tip is determined by the height of the drip chamber (head pressure). The drip chamber hangs from the bottle on the Programmable Power Pole. It is recommended that at the beginning of a procedure, the irrigation solution level in the drip chamber be located approximately 65-70 cm above the patient's eye level.

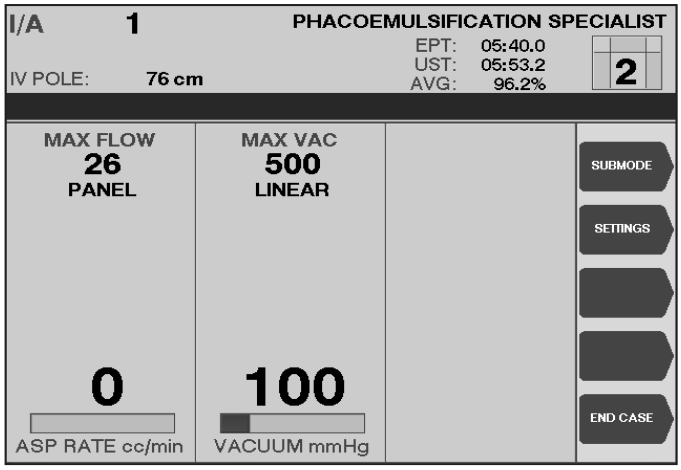
The irrigation tubing runs through the tubing manifold, and irrigation is controlled by the foot pedal. When the foot pedal is pressed, the pinch valve is opened and the irrigation fluid flows. Irrigation runs in foot pedal positions 1, 2 and 3.

There are no phaco system settings or adjustments associated with Irrigation, since the bottle height adjustment controls the fluid flow.

Aspiration Flow - A peristaltic pump provides the necessary aspiration flow to withdraw fluid and lens material from the eye chamber through the handpiece. With this aspiration flow system, vacuum builds when the aspiration port is blocked or occluded. The vacuum reduces as the occlusion clears.

Venting - As discussed earlier in this section, vacuum builds when the aspiration port is blocked or occluded by tissue or other material. The aspiration flow system fluid vents to the bottle when the foot pedal is released. Vacuum is also released in position 1 using pump rotation. This vacuum release gently releases material at the aspiration port, giving full control should the tip accidentally grab capsule or iris. Likewise, the internal fluidic system allows the desired vacuum level to be maintained simply by holding the foot pedal at a constant position. The two adjustments associated with aspiration flow are:

Note: Vacuum Mode and Flow Mode cannot be selected as "linear" at the same time.



Max Vac

Maximum vacuum determines the maximum suction force (limit) exerted on the aspirated fluid in the aspiration line. To assure fluidic balance, the aspiration vacuum limit is adjustable:

- From 0 to 500 mmHg, in increments of 5.
- Maximum Vacuum can be Panel or Linear.

Irrigation/Aspiration (Cont.)

Max Vac (Cont.)

The maximum vacuum is indicated by the MaxVac display. In Linear Vacuum, as the foot pedal is pressed through positions 2 and 3, the vacuum level travels between 0 mmHg and the maximum preset level as occlusions at the aspiration port occur. In other words, the vacuum level is linear with respect to foot pedal position. The actual vacuum level is indicated by the vacuum progress display on the front screen.

Max Flow

Flow (Aspiration Flow Rate) is the speed at which material is evacuated from the eye through the aspiration line. It is adjustable from 0 to 50 cc/minute in 2 cc increments, and may be PANEL or LINEAR. The flow rate reduces as the vacuum approaches the maximum vacuum.

Panel Flow

When Linear Vacuum is selected, flow is at the panel setting. PANEL flow provides constant evacuation at the preset flow rate.

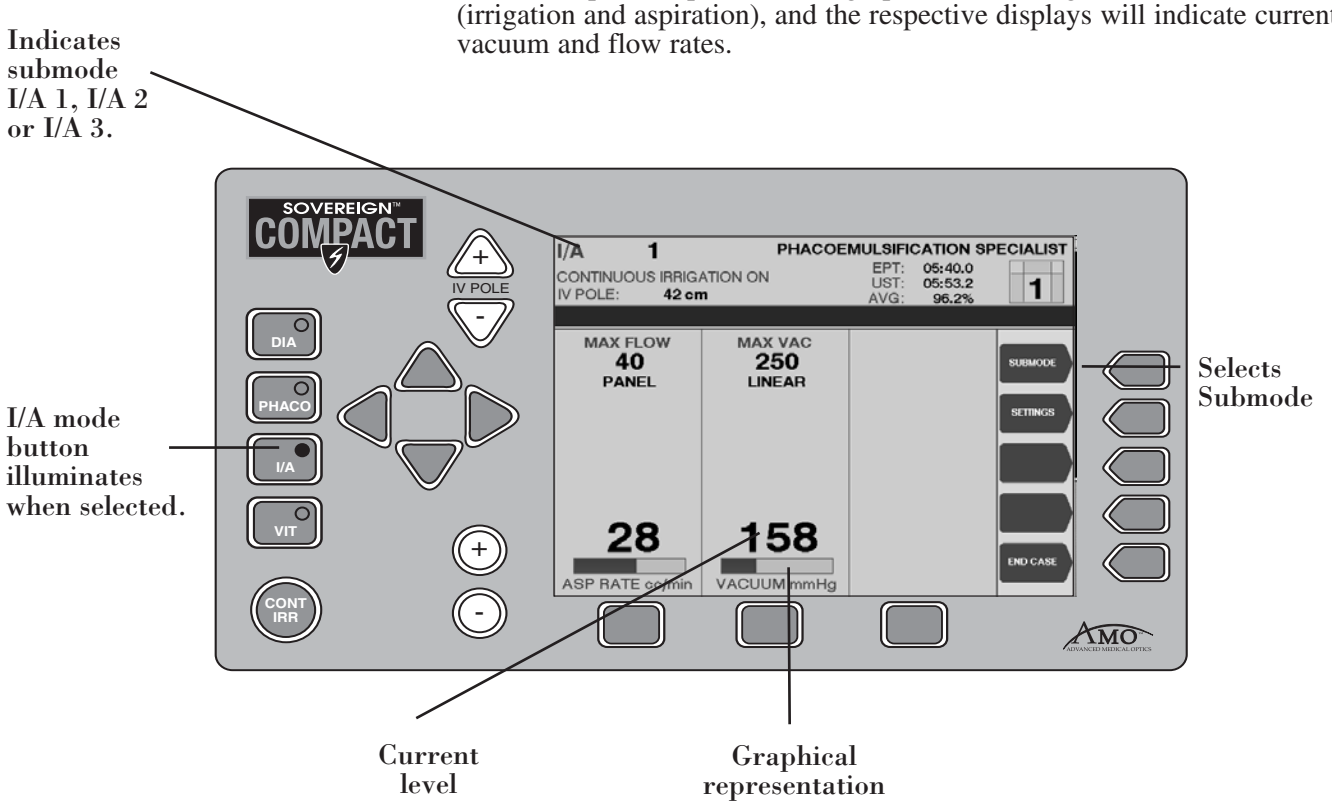
Note: Vacuum Mode and Flow Mode cannot be selected as "linear" at the same time.

Linear Flow

When LINEAR Flow is selected, the flow increases from the minimum (0 cc/min) to the maximum preset flow rate as the foot pedal is pushed through positions 2 and 3. A higher flow rate (as delivered via the foot pedal) results in a quicker vacuum rise time. Likewise, a slower flow rate results in a slower vacuum rise time.

Using Irrigation and Aspiration

1. Select I/A MODE on the front panel. The displays will indicate Irrigation and Aspiration Flow current settings.
2. Irrigation and Aspiration Flow will be indicated by the bars and displays as the foot pedal is pressed through positions 1 (irrigation), and 2 (irrigation and aspiration), and the respective displays will indicate current vacuum and flow rates.

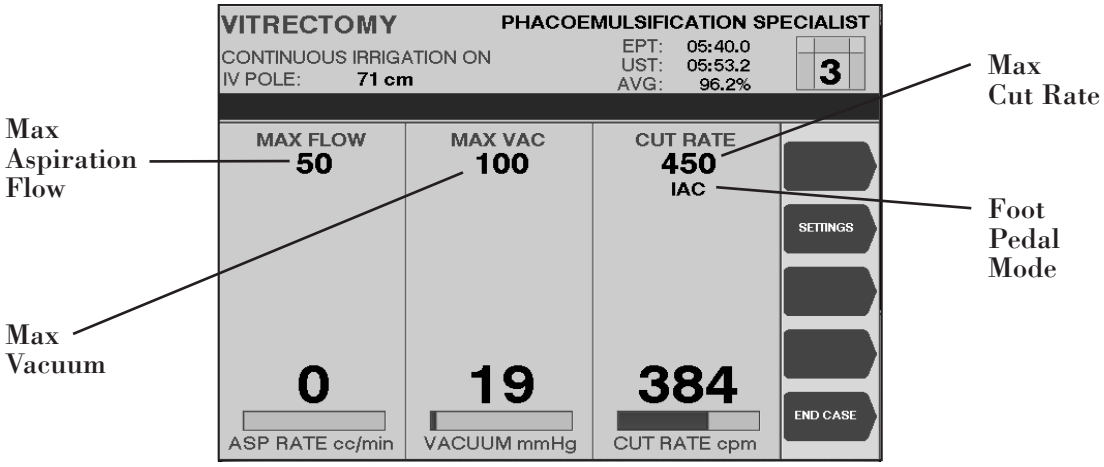


Vitrectomy

The SOVEREIGN™ COMPACT System uses an Oscillating (TAC) vitrectomy cutter. Handpieces are designed for cutting vitreous during anterior segment surgery and operate in conjunction with the Irrigation/Aspiration modes. The cutting speed can be varied using the front panel adjustments. There are 6 adjustments related to the Vitrectomy Mode:

- Max Asp Rate
- Max Vacuum
- Cut Rate
- Vacuum Mode
- Flow Mode
- Foot Pedal Mode

The foot pedal can be programmed as ICA, IAC, or Side Switch (SIDE VIT) Vitrectomy operation. These are explained below.



Asp Rate

The Flow rate, which operates as described in "Irrigation/Aspiration" mode, is adjustable from 0 to 50 cc/minute, in 2 cc increments.

Max Vac

Maximum Vacuum operates exactly as the MaxVac described in the "Irrigation/Aspiration" mode. It is adjustable from 0 to 500 mmHg.

Cut Rate

The Cut Rate of the oscillating cutter can be varied from 100 to 600 CPM.

ICA and IAC Foot Pedal

In VITRECTOMY, you may choose between ICA, IAC or Side vitrectomy, which determines how the foot pedal controls vitrectomy.

ICA

Footpedal positions correspond to:

- I (Irrigation in footpedal position 1)
- C (Irrigation and Cutting in footpedal position 2)
- A (Aspiration, Irrigation and Cutting in footpedal position 3)

IAC

Footpedal positions correspond to:

- I (Irrigation in footpedal position 1)
- A (Irrigation and Aspiration in footpedal position 2)
- C (Irrigation, Aspiration and Cutting in footpedal position 3)

Side Vit

Cutting occurs when right side switch is activated and held to continue cutting.

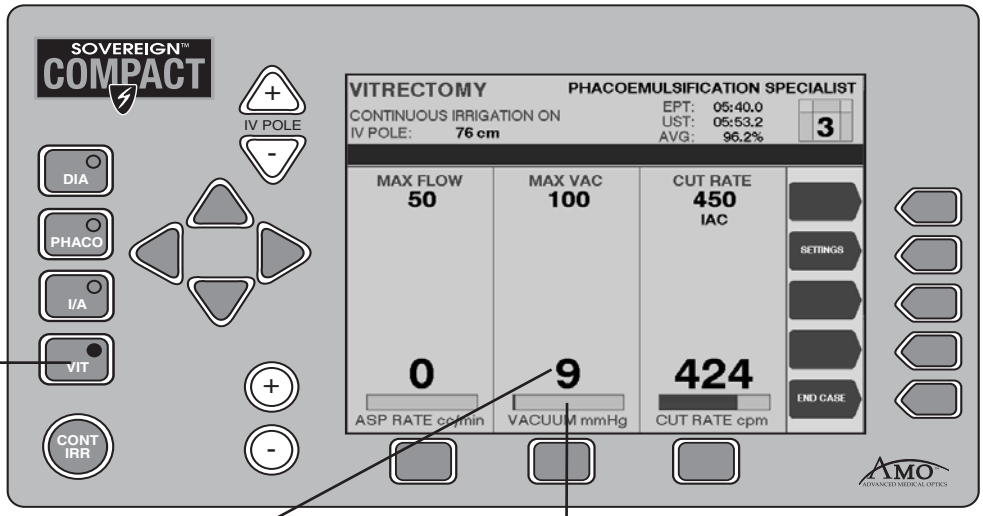
Vitrectomy (Cont.)

Foot Pedal Positions	Vitrectomy Modes: ICA	IAC	SIDE
1	Vit Irrigation	Vit Irrigation	Vit Irrigation
2	Irrigation/Cut	Irrigation/ Aspiration	Irrigation/ Aspiration
3	Irrigation/Cut /Aspiration	Irrigation/ Aspiration/Cut	

In SETTINGS the side switches can be turned ON or OFF. The side switches still work for SIDE VIT in VITRECTOMY, even if turned OFF for MMP in SETTINGS.

Using Vitrectomy

1. Select the Vitrectomy mode. The current flow, vacuum and CPM (CUT RATE) settings will be displayed.



VIT mode button illuminates when selected

Current level

Graphical representation

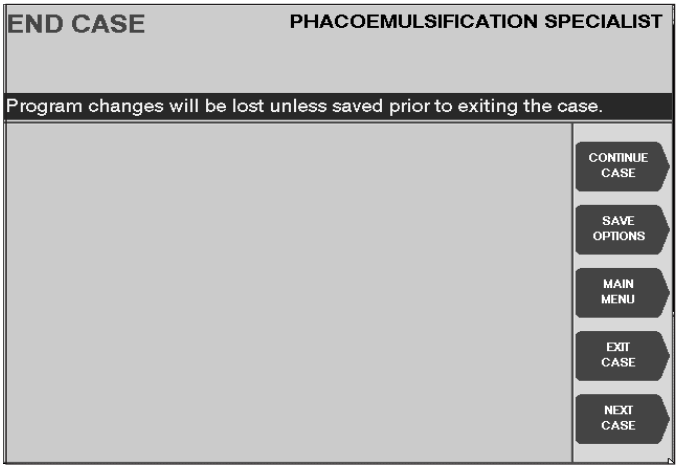
2. Press the foot pedal to activate the vitrectomy cutter.

Vitrectomy (Cont.)

CAUTION

THE PHACO AND VITRECTOMY HANDPIECES SHOULD NEVER BE ACTIVATED WITH THEIR TIPS IN THE AIR. DOING SO WILL DRASTICALLY REDUCE THEIR USEFUL LIFE. IF POWER IS TO BE INTRODUCED TO THE PHACO OR VITRECTOMY HANDPIECES, THEIR TIPS SHOULD BE IN A TEST CHAMBER FILLED WITH IRRIGATING SOLUTION, IN A CONTAINER OF IRRIGATING SOLUTION OR IN THE PATIENT'S EYE.

End Case



At the end of the procedure, press END CASE. Under SAVE OPTIONS, you may SAVE CHANGES to the selected program/surgeon name or SAVE AS to a desired surgeon name.

- CONTINUE CASE - Continue operating.
- SAVE OPTIONS - Proceed to SAVE screen.
- MAIN MENU
- EXIT CASE - Terminate case, reset all timers and redisplay the MAIN MENU.
- NEXT CASE - Use to reset the phaco and foot pedal timers, to reset any temporary settings during surgery and to prepare for the next surgical procedure (goes to PRIME/TUNE).

7 RECOMMENDED SETTINGS

This section gives recommended settings determined from clinical testing for all of the adjustable features. We recommend that you begin operating your SOVEREIGN™ COMPACT System using the AMO Defaults, then make adjustments to the settings as you become more comfortable with the machine and its responsiveness. You can then save your preferences using the "Surgeon Name" and "Save" features described in Section 5.

- Power IV Pole Heights
- Diathermy
- Phacoemulsification
- Irrigation/Aspiration
- Vitrectomy
- Other Settings

This information is more detailed and applies to the individual adjustments. As you become more and more proficient with your SOVEREIGN™ COMPACT System, you may find this specialized reference information helpful in developing your own settings.

Power IV Pole Heights

Suggested Programmable Power Pole heights for the different operating procedures are as follows:

Procedure	Appropriate Height
Phaco	70 cm
I/A	70 cm
Vitrectomy	30 cm

Diathermy

2 Sub-Modes in Diathermy

The purpose of diathermy is to stop bleeding in tissues by causing rapid coagulation. Pulses of high alternating voltage are applied to the tip of the diathermy forceps. The energy transferred to the tissue by the resulting spark or dielectric breakdown coagulates the tissue.

Tissue shrinkage that occurs during diathermy can induce astigmatism. For this reason, the least amount of power which produces the desired results should be used.

Figure 7.1
Diathermy Settings

Mode	Parameter	Available	Recommended Settings	
			D1	D2
Diathermy	Power Delivery Max Power	Linear, Panel Burst 5 to 100%	LIN 50%	BURST 50%

Phacoemulsification

The purpose of phacoemulsification is to disintegrate the cataract tissue in the eye and remove the debris. The Phacoemulsification Ultrasonic Handpiece has a sharp-ended hollow needle that vibrates longitudinally at an ultrasonic frequency. The rapid movement of the needle and the resulting cavitational energy disintegrates the cataract when they come in contact. The debris is removed by suction through the hollow needle (aspiration). The resulting loss in volume of the anterior chamber is compensated by incoming saline solution (irrigation).

4 Sub-Modes in Phaco

Sub-Modes - There are four (4) Phaco Sub-Modes. Within each sub-mode, there are programmable parameters for Unoccluded and Occluded phaco.

Phaco Power is a combination of stroke length, frequency and handpiece efficiency. A preset power setting of 30% using linear control allows you the ultimate control during phaco. Adjustments to phaco power will depend on various factors including nuclear density, surgeon preference and experience.

Figure 7.2
Phaco Settings

Mode	Parameter	Available Settings	Recommended
Phaco Unoccluded Settings	Max Power	0-100%	30
	Phaco Power	Linear, Panel	LIN
	Power Delivery	Continuous Short Pulse Long Pulse Low Power Pulse High Power Pulse Single Burst Multi-Burst Continuous Burst Continuous WHITESTAR™* Technology Pulse WHITESTAR™* Technology	CON
	Delivery Type Short Pulse	1-14 pps	6
	Delivery Type Long Pulse Rate	1-6 pps	6
	Delivery Type WHITESTAR™* Technology	C/F, B/D, C/B, C/D, D/B, C/L, D/L, C/I	C/F
	Delivery Type Pulse WHITESTAR™* Technology	1-5 pps	4
Phaco Occluded Settings	Max Power	0-100%	35
	Phaco Power	Linear, Panel	LIN
	Delivery Type	Continuous Short Pulse Long Pulse Low Power Pulse High Power Pulse Single Burst Multi-Burst Continuous Burst Continuous WHITESTAR™* Technology Pulse WHITESTAR™* Technology	LONG PULSE
	Delivery Type Short Pulse Rate	1-14	6
	Delivery Type Long Pulse Rate	1-6 pps	6
	Delivery Type WHITESTAR™* Technology	C/F, B/D, C/B, C/D, D/B, C/L, D/L, C/I	C/F
I/V Pole Height		0-76 cm	

*Optional enhancement; check with your local AMO representative for availability

Irrigation/Aspiration

The purpose of Irrigation and Aspiration is for removal of remaining thin tissue from the walls of the capsule. Typically, a special handpiece with tip is used that has the aspiration port on the side. This enables the surgeon to safely polish the posterior capsule without risking puncture.

3 Sub-Modes in I/A

During cortical removal, the maximum vacuum preset level can be set up to 500 mmHg. Actual vacuum rise is controlled by foot pedal and aspiration tip occlusion. You may elect to continue control in the lower vacuum range during capsule polishing (using the aspiration tip with the port up) via the foot pedal actuating fluidic venting. Or, you may prefer to turn the maximum vacuum down to 100 mmHg during the capsule polishing technique.

Figure 7.3 Irrigation/Aspiration Settings

Mode	Parameter	Available Settings	Recommended
Irr/Asp	Bottle Height	0-76 cm	71 cm
	Vacuum Mode	Linear, Panel	LIN
	I/A Mode	Linear, Panel	PAN
	Max Vac	0-500 mmHg	500
	Max Flow	0-50 cc/min	26

Vitrectomy

The purpose of the vitrectomy handpiece is to cut and remove the vitreous humor present in the anterior chamber of the eye. The standard oscillating cutter has a motor driven inner cutting blade that moves in a repeatedly reversing single revolution against the inner wall of the outer tube. Aspiration is connected to the handpiece. As the vitreous humor is cut, it is sucked into the handpiece.

Low settings for cutting, vacuum and pump speed are recommended to assure proper function of the vitrectomy cutter. These low settings allow entry of vitreous strands and efficient cutting without pulling on the strands. Adjustments can be made during the vitrectomy procedure based on surgeon preference.

Figure 7.4 Vitrectomy Settings

Mode	Parameter	Available Settings	Recommended
Vitrectomy Cut Rate	Cut Rate	Oscillating 100-600 cpm	450
	Vitrectomy	ICA, IAC, Side VIT Cut Mode	ICA

Figure 7.5
Settings

Parameter	Available Setting	Recommended
Foot Pedal Continuous Irrigation	On, Off	Off
Reflux Foot Switch	On, Off	On
Side Foot Switches	On, Off	On
Foot Pedal Feedback	On, Off	Off
Foot Pedal Threshold FP1	0-FP2	10%
Foot Pedal Threshold FP2	FP1-FP3	20%
Foot Pedal Theshold FP3	FP2-100%	45%
Sound Volume	0 (None) - 10 (High)	3
Vacuum Audio Signal	On, Off	On

8 CHECK-OUT, PRECAUTIONS AND WARNINGS

In this section you will find:

- System Check-Out
  - Irrigation/Aspiration
  - Phacoemulsification
  - Diathermy
  - Vitrectomy
- Safety Precautions
- Warnings
- Symbol Definitions

System Check-Out

The purpose of the check-out sequence is to verify that the SOVEREIGN™ COMPACT System is installed and operating properly. The checkout sequence should be performed at least prior to the first case of the day and any time program changes are made as outlined in the following steps. The I/A function and handpiece are tested first, then the Phaco function and handpiece, so that the phaco handpiece (which is used first) will be set up and ready for surgery.

If any of the check-out steps are not successfully performed, they should be repeated. If the instrument is still not working correctly, refer to Section 10, Error Messages and Troubleshooting.

Set-Up and Prime/Tune

Refer to Section 3 and 6 for instructions on installing the tubing and priming/tuning the system.

Irrigation/Aspiration

1. Move the tubing to the I/A handpiece.
2. Select I/A mode. Holding test chamber near tip, press and hold foot pedal in position 2. Observe the irrigation flow and pump turning.

Phacoemulsification

1. Move the irrigation and aspiration tubing to the Phacoemulsification Ultrasonic Handpiece.
2. Screw the ultrasonic needle onto the handpiece, using your fingers to first engage the screw thread, then use the tip wrench to tighten the needle so that it is quite snug. Screw the irrigation sleeve assembly over the needle.
3. Select the Phacoemulsification mode on the front panel. Press and hold the foot pedal in position 2. Observe the irrigation flow and pump turning. Holding the handpiece approximately at patient's eye level, fill the test chamber with irrigation fluid and place the test chamber over the irrigation sleeve.
4. Occlude the aspiration line just below the ultrasonic handpiece. The actual vacuum level should rise to the preset level.
5. Release the occlusion and watch the test chamber to make sure that it does not collapse. A slight shallowing of the chamber is normal.
6. To test irrigation, pinch the irrigation tubing at the I/A handpiece and watch for the test chamber to collapse. Release the irrigation line and the test chamber should refill.
7. Press NEXT CASE to reset the phaco timer.
8. Phacoemulsification check-out is complete.

Diathermy

1. Connect Diathermy forceps to cable and cable to front panel.
2. Select the Diathermy mode on the SOVEREIGN™ COMPACT System front panel.
3. Depress the foot pedal. A tone should be heard when the foot pedal is pressed.

CAUTION

IF A TONE IS NOT HEARD WHEN THE FOOT PEDAL IS PRESSED AND VOLUME ADJUSTMENT IS UNSUCCESSFUL, THE MODE IS NOT FUNCTIONING PROPERLY. REFER TO PAGE 10-8 IN SECTION 10 FOR THE APPROPRIATE CORRECTIVE ACTION.

Vitrectomy

1. Connect I/A tubing to the vitrectomy handpiece.
2. Connect tubing to vitrectomy receptacle on the left front of the SOVEREIGN™ COMPACT System.
3. Select Vitrectomy Mode on front panel.
4. Submerge the cutter port in irrigation solution. Press the foot pedal to position 2 or 3. Observe:

    a. irrigation fluid flows.
    b. aspiration line is full and clear of air.
    c. motor is actuated (slight sense of motion of the handpiece).
    d. cutter blade operates.

5. Vitrectomy check-out is complete.

SAFETY PRECAUTIONS FOLLOW ON NEXT PAGE

SAFETY PRECAUTIONS

Now that you have correctly set up the system and verified that all of the functions are operating properly, you are almost ready to proceed with using your SOVEREIGN™ COMPACT System.

Read the following Safety Precautions and Warnings very carefully before using your SOVEREIGN™ COMPACT System in surgery.

1. The SOVEREIGN™ COMPACT System is equipped with 3-prong plugs which should be plugged into an outlet with a ground receptacle. If the plug does not fit the outlet, contact an electrician. DO NOT defeat or remove the ground pin.
2. Do not use extension cords with your machine.
3. Do not overload your AC electrical outlet.
4. If the cord or plug is damaged, do not continue using the instrument. Electric shock or fire hazard may result. Call AMO to order a new cord.
5. The instrument has ventilation openings at the rear of the console to allow the release of heat generated during operation. If these openings are blocked, heat build-up can cause system failures which may result in a fire hazard.
6. Do not try to roll the SOVEREIGN™ COMPACT System cart on deep pile carpets or over objects on the floor such as cables and power cords.
7. Do not place the instrument on uneven or sloped surfaces.
8. Do not use disposables, accessories or other surgical instruments that are not designed for this system. Use only parts recommended by AMO to achieve optimum performance and safety.
9. Do not operate the SOVEREIGN™ COMPACT system in a condensing environment. Take care to protect the instrument from fluid sprays or fluid buildup.
10. To protect patient from contaminated fluids or handpieces, use only:
    - sterile tubing sets
    - sterile irrigation fluid
    - sterile handpieces
11. Use caution when extending, retracting or swiveling the mayo stand articulating arm. Stay clear of hinged hardware.
12. Use caution when handling handpieces with sharp edges or pointed tips.
13. Always replace the drain bag with a clean bag between cases.
14. Wrap the excess power cord neatly around the cord wrap on the back of the I/V pole.

SAFETY PRECAUTIONS

Changing Irrigation	When lowering or raising the irrigation solution bottle to decrease or increase fluid flow and pressure, exercise extreme caution. Lowering the bottle too much can cause anterior chamber collapse. Raising the bottle too high can cause a deep or bulging chamber.
Phacoemulsification Without Adequate Irrigation	Operating phacoemulsification without adequate flow may result in elevated temperature of the tip and subsequent damage to the eye tissue or could cause chamber collapse. Confirm that there is irrigation flow prior to initiating phacoemulsification. A tight wound or the angle of the needle next to the wound can also constrict the irrigation flow by pinching off the irrigation sleeve assembly on the needle of the phaco handpiece.
Power Failure During Surgery	Should you momentarily lose power during a procedure, you will need to withdraw the handpiece from the eye. Release the footpedal to position 0 and when power is restored, re-select PROGRAM and press PRIME/TUNE or I/A PRIME to reprime the fluids. BYPASS PRIME may be used. Reselect the function you are using (Phaco, I/A, Vitrectomy or Diathermy).
Connecting Handpieces	It is very important that the electrical connectors on the handpieces are completely dry prior to connecting them to the SOVEREIGN™ COMPACT System receptacles. You may receive a "Phaco Handpiece Ground Fault Error" message if the connector is wet.
Handling the Phacoemulsification Ultrasonic Handpiece	The ultrasonic handpiece is a very delicate instrument and should be handled with EXTREME care. If it is dropped or receives any other significant impact, it will not work properly. The ultrasonic titanium phaco tip should never touch any solid material while in use. Always flush the handpiece immediately following surgery. See cleaning instruction given on page 9-2. Handpieces may be extremely hot immediately after sterilization. Use care and caution when handling.
Phaco and Vitrectomy Operation	The Phaco and Vitrectomy handpieces should never be activated with their tips in air. Doing so will drastically reduce their useful life. If power is to be introduced to the Phaco or Vitrectomy handpieces, their tips should be in a test chamber filled with irrigating solution, in a container of irrigating solution, or in the patient's eye.
Vitrectomy	Failure to properly attach the tubing to the appropriate vacuum or pressure source will affect the vitrectomy handpiece operation. Be sure to read the handpiece package insert for correct assembly and connection procedures.

SAFETY PRECAUTIONS

Diathermy	Upon entering diathermy mode, an audible tone should be confirmed. Also, whenever diathermy power is applied, an audible tone should be heard. The diathermy cable should be checked periodically for damage. If the cable shows signs of damage, replace it immediately with the same type of cable. Use of other types of cables may affect the diathermy performance. During surgery, the diathermy output power should be as low as possible for the intended purpose. AMO recommends 30% setting to start. The patient should not come into contact with ungrounded metal parts when diathermy is being used. The diathermy cable should be positioned in such a way that contact with the patient or other leads is avoided. For proper operation of the diathermy, replace handpiece with same type.
Power IV Pole	Do not exceed maximum weight of 11 kg (2.51 lbs.) on the IV pole bottle holder.
Foot Pedal	Never handle the footpedal by its power cord.

WARNINGS FOLLOW ON NEXT PAGE

WARNINGS

WARNING: All personnel should read and understand the instructions in this manual before the system is used. Failure to do so may result in the improper operation of the system.

WARNING: DO NOT attempt to use the system if it fails to perform properly as stated in this manual.

WARNING: DO NOT use the system in the presence of flammable anesthetics, or other flammable gases, near flammable fluids or objects, or in the presence of oxidizing agents, as fire could result.

WARNING: This unit may interfere with any cardiac pacemaker fitted to the patient, therefore qualified advice should be obtained prior to such use.

WARNING: The patient should not come into contact with metal parts which are earthed or have appreciable capacitance to earth. The use of an antistatic mat for this purpose is recommended.

WARNING: Monitoring electrodes or other types of equipment should be placed as far from those of the SOVEREIGN™ COMPACT System as possible. High current limiting devices are recommended for the protection of such systems.

WARNING: The output power selected should be as low as possible for the intended purpose.

WARNING: Although this unit complies with all EMI standards and requirements, it is possible that this unit could interfere with other types of electronic equipment.

WARNING: Skin to skin contact on the patient, e.g., between the arms and the torso is not recommended.

Note: The unit contains no neutral electrode.
Note: The diathermy output is bipolar.
Note: It is recommended that the condition of all inter-connecting and handpiece cables be checked on a regular basis.

WARNING: Risk of burns and fire. Do not use near conductive materials such as metal bed parts, inner spring mattresses, and the like. Renew electrode cables on evidence of deterioration.

WARNING: Hazardous electrical output. This equipment is for use only by qualified personnel.

WARNING: Disconnect power before servicing.

WARNINGS

WARNING: Sterility assurance is the responsibility of the user. All non-sterile accessories should be sterilized prior to use.

WARNING: Prior to using any invasive portions of the handpiece assembly, examine under the microscope for any obvious damage, oxidation, or the presence of foreign material. If any questionable characteristics are noted, use a backup handpiece for surgery. Use of contaminated or damaged system accessories may cause patient injury.

WARNING: Use of non-AMO aproved products with the SOVEREIGN™ COMPACT System, may affect overall system performance and is not recommended. AMO cannot be responsible for system surgical performance if these products are utilized in surgery.

WARNING: Not recommended for use in condensing environment. If exposed to condensing environment allow to equilibrate to typical operating room conditions prior to use.

WARNING: This HIGH FREQUENCY (HF) SURGICAL EQUIPMENT is specified for use without a NEUTRAL ELECTRODE.

WARNING: Failure of the HIGH FREQUENCY (HF) SURGICAL EQUIPMENT could result in an unintended increase of output power.

WARNING: Interference provided by the operation of the HF SURGICAL EQUIPMENT may adversely influence the operation of other electronic equipment.

Symbol Definitions

The following symbols appear on the SOVEREIGN™ COMPACT System front and back panels:

Symbol on power switch indicates Power is ON.

Symbol on power switch indicates Power is OFF.

Indicates that there are important operating and maintenance instructions included in the Owner's and Operator's Manual.

Indicates the presence of uninsulated high voltage inside the instrument. Risk of electric shock. Do not remove the instrument cover.

Indicates fuse.

Single phase alternating current.

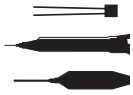
Patient applied part is isolated from earth ground.

Patient applied part is grounded OR no direct electrical energy is involved.

Foot pedal connection.

Communications Port

Remote



Programmable Power Pole

Diathermy Forceps (Diathermy Receptacle)

Phaco Handpiece Receptacle

Vitrectomy Cutter (TAC) Receptacle

Potential Equalizer

Indicates compliance with the Medical Device Directive.

Indicates product listed with Intertek Testing Services.

(Continued on next page)

Symbol Definitions (Cont.)

Indicates compliance with IEC 60601-1-2:2001, "Electromagnetic Compatibility Requirements and Tests for Medical Electrical Equipment"

Separate Collection Required

Below the hazardous materials limits in SJ/T11363-2006 (China)

Environment Friendly Use Period, in Years

对于中国规章制度：电子信息产品污染控制管理办法

有毒有害物质名称及含量的标识格式

部件名称	有毒有害物质或元素					
	铅（Pb）	汞（Hg）	镉（Cd）	六价铬（Cr6+）	多溴联苯（PBB）	多溴二苯醚（PBDE）
静脉输液架	x	o	o	x	x	x
外壳	x	o	o	x	x	x
主板	x	o	o	o	x	x
辅板	x	o	o	o	x	x
马达	x	o	o	o	o	o
电源	x	o	o	o	x	x
开放式脚踏板	x	o	o	o	o	o
封闭式脚踏板	x	o	o	x	o	o
小车	o	o	o	x	o	o
遥控器	x	o	o	o	x	x

o：表示该有毒有害物质在该部件所有均质材料中的含量均在SJ/T 11363-2006标准规定的限量要求以下
x：表示该有毒有害物质至少在该部件的某一均质材料中的含量超出SJ/T 11363-2006标准规定的限量要求
（企业可在此处，根据实际情况对上表中打“×”的技术原因进行进一步说明）

For Chinese Regulation: Administrative Measure on the Control of Pollution Caused by Electronic Information Products

Names and Content of Toxic and Hazardous Substances or Elements

Parts Name	Toxic and Hazardous Substances or Elements					
	Pb	Hg	Cd	Cr6+	PBB	PBDE
IV Pole	x	o	o	x	x	x
Housing	x	o	o	x	x	x
Motherboard	x	o	o	o	x	x
Secondary Board	x	o	o	o	x	x
Motor	x	o	o	o	o	o
Power Supply	x	o	o	o	x	x
Open Toe Foot Pedal	x	o	o	o	o	o
Closed Toe Foot Pedal	x	o	o	x	o	o
Cart	o	o	o	x	o	o
Remote Control	x	o	o	o	x	x

o: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-2006
x : Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in SJ/T11363-2006 (Enterprises may further provide in this box technical explanation for marking “X” based on their actual conditions.)

9 CARE AND CLEANING

In this section you will find:

- Cleaning Procedures
  - Phaco Handpiece
  - Irrigation/Aspiration Handpiece
  - Diathermy Handpiece
  - Vitrectomy Handpiece

- Sterilization Procedures
  - Gravity Displacement Sterilization
  - Prevacuum Sterilization
  - Storage After Sterilization

- SOVEREIGN™ COMPACT System Cleaning and Care

Cleaning Procedures

All previously used reusable items should be handled according to ANSI/AAMI ST46 "Good Hospital Practice: Steam Sterilization and Sterility Assurance," section 5.4. Reuse information may be found in the Directions for Use for the particular product. All single use items or items which have completed their recommended useful life should be disposed of in accordance with accepted hospital practices and procedures and local governing ordinance and recycling plans. These items may include, but are not limited to, waste materials, waste collection bags, tubing, tip cap sleeves and test chambers.

NOTE: Inspect the Diathermy, Vitrectomy and Phaco handpiece cables for possible damage on a daily basis.

Phacoemulsification Ultrasonic Handpiece

The following cleaning procedures for the SOVEREIGN™ COMPACT System handpieces should be implemented immediately after use. The straight-through design of the Phacoemulsification Ultrasonic Handpiece makes cleaning easy and greatly reduces the likelihood of handpiece clogging. However, to maximize the life of your instruments, you should clean the instruments immediately after use. Likewise, failure to properly clean the instrument can result in tissue buildup and dangerous cross-contamination. The following cleaning procedure is to be performed at the end of each surgical case.

NOTE: Irrigating salt solutions will tarnish and pit metals, thus hastening deterioration. Proper cleaning of instruments will prolong their useful life. AMO recommends using sterile distilled water to clean the handpieces and accessories.

1. With the tip cap sleeve and phaco tip still in place on the handpiece, inject 60 cc of distilled water through the irrigation line of the phaco handpiece with a syringe. Flush with air.
2. Next, inject 60 cc of distilled water through the aspiration line of the phaco handpiece. It is helpful to use a female/female connector to attach the syringe to the aspiration line. Flush with air.
3. Carefully remove the phaco tip cap sleeve and phaco tip from the handpiece for disposal or autoclaving and storage.
4. The phaco test chamber is cleaned by injecting distilled water into it with the syringe and emptying, then repeating 3 to 4 times.
5. The phaco tips are cleaned by first aspirating distilled water through the tip into the syringes; this clears any debris from within the tip and prevents plugging of the suction port.
6. Gently wipe the power cable of the handpiece with gauze soaked in distilled water.

WARNING: Improper/inadequate cleaning may result in particulate matter adhering to the instrument and exfoliation of particles into the surgical field. In addition, the function and life expectancy of the phaco handpiece may become compromised.

CAUTION: Do not clean the phaco handpiece with any type of ultrasonic cleaning device; it will damage the piezoelectric crystals.

Irrigation/Aspiration Handpiece

1. It is extremely important that the I/A Handpieces are back-flushed immediately at the conclusion of the procedure.

   Use a 10cc syringe with distilled water and flush the water from the back of the handpiece through the tips. This process should be performed at least two times through both the irrigation and aspiration channels.

   Note: You may use other available AMO products designed for this process (I/A Cleaning Kit, AMO Part No. OM05510114).

2. Assure I/A handpieces are dry when stored.

Diathermy Handpiece

Clean the diathermy handpieces using the same procedures you use to clean other ophthalmic instruments.

NOTE: Inspect the Diathermy, Vitrectomy and Phaco handpiece cables for possible damage on a daily basis.

Vitrectomy Handpiece

The TAC electronic oscillating vitrectomy handpiece is a delicate reusable cutter.

1. **IMMEDIATELY** after the case (to prevent solidification of vitreous within the handpiece), remove the infusion sleeve and gently flush at least 60 cc of distilled water through the handpiece suction line (red marking).
2. Flush the handpiece suction line with 60 cc of alcohol.
3. Flush the handpiece suction line with air to dry. It is helpful to use a female/female connector for this procedure.
4. Wipe the power cable of the handpiece with gauze soaked in distilled water.
5. Flush the infusion sleeve with 60 cc of distilled water.

CAUTION

DO NOT TOUCH THE EDGE OF THE SINK OR ANY HARD OBJECT WITH THE CUTTING TIP OF THE VITRECTOMY HANDPIECE - IT CAN BE EASILY DAMAGED, AND IS VERY EXPENSIVE TO REPAIR.

Sterilization Procedures

AMO recommends that you follow the sterilization procedures outlined in this section to maximize the life of your SOVEREIGN™ COMPACT System instruments.

All parts should be cleaned thoroughly prior to sterilization, and all sterilization vessels should be validated prior to use.

CAUTION

- **DO NOT STERILIZE THE HANDPIECES PRIOR TO PERFORMING THE CLEANING PROCEDURES DESCRIBED IN SECTION 9.**
- **THE STORAGE CASES PROVIDED ARE NOT AUTOCLAVABLE.**

OPO65 Reusable Tubing is recommended for single-patient use or limited reuse (up to 20 cases). There are a variety of ways to reuse the reusable tubing:

1. Use one set of tubing per day; clean and autoclave between each case.
2. Use two sets of tubing per day and “leapfrog” the cases; one set can be cleaned and autoclaved while the other is being used.
3. Use one set of tubing for each case of the day. At the end of the day clean all sets of tubing and autoclave them in “peel-packs” for use on the next surgery day. This method gives the convenience of a disposable but maintains the cost-effectiveness of reusable. Again, a drying cycle at the end of autoclaving is suggested to remove moisture for storage.

The reusable components have been designed to withstand the parameters of accepted procedures as outlined in the AAMI Guideline for "Good Hospital Practice: Steam Sterilization Sterility Assurance," ST46-1993.

The following sterilization techniques, times, and temperatures should be used in order to ensure consistent product performance:

Gravity Displacement Sterilization - A type of sterilizer in which incoming steam displaces the residual air through a port or drain usually in or near the bottom of the sterilizer chamber. Typical operating temperatures are 121 to 123˚C (250 to 254˚F) and 132 to 135˚C (270 to 275˚F).

Prevacuum Sterilization - A type of sterilizer which relies on one or more pressure and vacuum excursions at the beginning and/or end of the cycle. This method of operation usually results in shorter cycle times because of the rapid removal of air from the chamber and the load by the vacuum system, the usually higher operating temperature (132 to 135˚C / 270 to 275˚F; 141 to 144˚C / 285 to 290˚F), and the shorter exposure time for porous loads.

NOTE: The aforementioned cycles require the product to be wrapped. Ensure that moisture is present prior to autoclavable sterilization.

Sterilization Procedures (Cont.)

In an emergency situation only Flash Sterilization in accordance with ANSI/AAMI ST37-1996 "Good Hospital Practice: Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use" may be used. The parameters for mixed porous and nonporous items should be used.

CAUTION

GAS STERILIZATION IS NOT RECOMMENDED.

Cooling is not necessary prior to reassembly; however, caution should be used to prevent burns.

WARNING: Sterility assurance is the responsibility of the user. All non-sterile accessories should be sterilized prior to use.

In addition, AMO recommends a terminal sterilization cycle in the autoclave after the final case of the day. This cycle should include a drying cycle to remove moisture from the tubing and handpiece for storage.

Devices undergoing sterilization should be thoroughly cleaned to minimize bioburden. Validation of the sterilization vessel and the sterilization cycle is the responsibility of the user.

1. After sterilization, store the instruments in a safe, clean environment. Keep them dry and free of dust. Make sure that the handpiece nose cone tips are adequately protected during storage.

2. Do not wind the Phacoemulsification Ultrasonic Handpiece cord too tightly. Treat it as you would a fiberoptic cable. Follow the natural curve of the cord and wind only as tightly as the natural curve of the cord (approximately 6 inch coiled cord diameter).

3. IMPORTANT! Handle the ultrasonic handpiece with extreme care. The piezoelectric crystal in the handpiece is very sensitive to shock. If the handpiece is dropped, it is possible that it will not function correctly. Should this happen, contact AMO for repair information or replacement.

SOVEREIGN™ COMPACT System Cleaning

- Turn the power switch on the back of the SOVEREIGN™ COMPACT System OFF before unplugging the machine.
- At the end of the day, thoroughly wipe down the machine, cart, power pole and foot pedal using a cloth dampened with a germicidal detergent and sterile distilled water. Be careful not to saturate any part of the machine or the foot pedal with liquid - excessive liquid can damage the SOVEREIGN™ COMPACT System electronics.
- Do not push or pull on system components.
- It is recommended that you leave the foot pedal and power cords connected to the machine and power pole to prevent loss and unnecessary wear on the electrical connectors.
- Although the foot pedal is water-resistant, please use care to insure that it is kept as dry as possible.

10 ERROR MESSAGES, TROUBLESHOOTING AND DIAGNOSTICS

In this section you will find:

- Most Common User-Correctable Problems

- Error Messages
  - General
  - Irrigation System
  - Aspiration System
  - Phacoemulsification System
  - Diathermy System
  - Vitrectomy System

- Diagnostics
  - Self Test
  - Foot Pedal Test
  - Console and Remote Test
  - Delete Surgeon Database
  - View Logs
  - View Software Versions
  - Set System Time
  - Upload/Download Files

- Fuse Replacement Procedure

If you have set up the SOVEREIGN™COMPACT System in accordance with the instructions given in this manual and have been unable to successfully complete the System Check-Out, the information presented in this section may be helpful to you. **Before calling AMO for technical service, consult this section to see if you can find a solution to the problem you are experiencing.**

Most Common User-Correctable Problems

Before you call AMO for service:

- Be sure that the SOVEREIGN™COMPACT System is plugged in.
- Be sure that there is electrical power to the receptacles.
- If no phacoemulsification, be sure that the phaco needle is tightened on the handpiece.
- If no phacoemulsification, be sure that the phaco needle is compatible with the handpiece (i.e., non-AMO phaco needle on an AMO handpiece may not work properly).
- If no phacoemulsification, confirm that phaco needle/handpiece has not been damaged by dropping or misuse.
- If no irrigation occurs, shake the drip chamber to confirm that the ball rattles freely. If it doesn't, replace it with another OPO60 tubing pack, or the Administration Set (OM2505191) if using the OPO65.

Advisory, Warning and Error Messages

The display on the SOVEREIGN™COMPACT System is capable of giving Status, Warning and Error Messages for certain problems. Frequently, the message will also present possible solutions or recommendations to clear the error. It may also indicate available options should a component or subsystem fail.

The messages are listed in the following pages with corrective action to be taken to clear the error.

Messages which read "Recycle Power" mean that you should turn the machine off and back on again. If you are not successful in correcting an error, be sure to document the message prior to calling AMO for Technical Service. This information will help service in diagnosing and correcting the problem.

Figure 10.1
System Operation Messages

ID#	Message	Probable Cause	Corrective Action
2	**PVD Initialization Failed**	Circuit board failure.	Recycle power.
4	**Fluidics Initialization Failed**	Circuit board failure.	Recycle power.
8	**Foot Pedal Not Connected**	Foot pedal connection loose.	Verify foot pedal connection. Recycle power.
9	**Foot Pedal Cal Error**	Foot pedal calibration issue.	Release foot pedal to FP0. Recycle power.
13	**Keyboard Controller Failure**	Circuit board failure.	Recycle power.
16	**Remote Not Connected**	Remote connection loose.	Verify remote connection. Recycle power. System will operate without remote.
20	**I/V Pole Not Connected**	I/V pole connection loose.	Verify connection. Recycle power. Normal message if system not configured with Programmable Power Pole. System will operate without power I/V pole.
21	**I/V Pole Failure**	I/V pole connection not verified.	Verify connection, if Programmable Power Pole is resident. Recycle power. System will operate without power I/V pole.
29	**Foot Pedal Inconsistency**	Foot pedal sensor position identification inconsistent.	Verify foot pedal connection. Recycle power.
35	**Doctor Program File Corrupt**	Corruption of doctor's program. Reprogram entries, if needed.	Restore Surgeon Database or Delete the Surgeon Database via system DIAGNOSTICS.
38	**Host SW File Corrupt**	Faulty software.	Recycle power.
42	**Self Test Failed**	One or more of Self Tests failed.	Refer to the actual error of the failed test.
44	**System Files Corrupt**	Faulty software.	Recycle power.
50	**Fluidics Not Primed**	Fluidics prime not verified.	Prime or reprime fluidics.
51	**Phaco Handpiece Not Tuned**	Phaco mode was selected without tuning handpiece.	Tune handpiece and retry phaco. Possible damage to handpiece cable. Try another handpiece.

Figure 10.1
System Operation Messages (Cont.)

ID#	Message	Probable Cause	Corrective Action
60	**Fluidics Not Initialized**	Circuit board failure.	Recycle power.
61	**PVD Not Initialized**	Circuit board failure.	Recycle power.
84	**I/V Pole Communication Stopped**	Circuit board failure. or loose connection.	Verify I/V pole connection. Recycle power. System will operate without power I/V pole.
91	**Software Failure Detected**	Faulty software.	Recycle power.
100	**Fluidics Communication Error**	Circuit board failure.	Recycle power.
101	**Fluidics Communication Error**	Circuit board failure.	Recycle power.
110	**Fluidics Subsystem Error**	Circuit board failure.	Recycle power.
111	**Fluidics Subsystem Error**	Circuit board failure.	Recycle power.
112	**Fluidics Communication Error**	Circuit board failure.	Recycle power.
181	**Fluidics Subsystem Failure**	Circuit board failure.	Recycle power.
182	**Pump Rotation Error**	Pump mechanically blocked or electrical fault.	1. Check tubing installation. 2. Recycle power.
183	**Vent Valve Error**	Valve mechanically stuck or wire broken to solenoid.	1. Check tubing installation. 2. Verify that vent valve toggle moves freely. 3. Recycle power.

Figure 10.1
System Operation Messages (Cont.)

ID#	Message	Probable Cause	Corrective Action
184	**Irrigation Valve Error**	Valve mechanically stuck or wire broken to solenoid.	1. Check tubing installation. 2. Verify that the irrigation valve toggle moves freely. 3. Recycle power.
186	**Fluidics Subsystem Error**	Circuit board failure.	Recycle power.
192	**Irrigation Blocked**	Valve mechanically stuck, tubing kinked, tubing not routed properly, or clogging.	1. Verify that the irrigation valve toggle moves freely. 2. Check tubing for kinks, or clogging and/or proper installation.
193	**Fluidics Subsystem Error**	Circuit board failure.	Recycle power.
200	**PVD Communication Error**	Circuit board failure.	Recycle power.
201	**PVD Communication Error**	Circuit board failure.	Recycle power.
202 203, 204, 205	**Phaco Handpiece Error**	Circuit board failure or bad handpiece.	1. Retune handpiece. 2. If retune is unsuccessful, recycle power and retune handpiece.
210	**PVD Subsystem Failure**	Circuit board failure.	Recycle power.
211	**PVD Subsystem Failure**	Circuit board failure.	Recycle power.
212	**PVD Communication Error**	Circuit board failure.	Recycle power.
281	**PVD Subsystem Failure**	Circuit board failure.	Recycle power.
282	**Handpiece Ground Error**	Moisture at connector site. Failed handpiece.	Dry connector. Retune handpiece or replace handpiece.

Figure 10.1
System Operation Messages (Cont.)

ID#	Message	Probable Cause	Corrective Action
283	Phaco Subsystem Failure	Circuit board failure.	Recycle power.
285	Check Phaco Handpiece Tip	Phaco needle broken or loose.	Retighten or replace needle. Retune handpiece.
286	Phaco Handpiece Error	Circuit board failure or faulty handpiece.	1. Retune handpiece. 2. If retune is unsuccessful, recycle power and retune handpiece.
287	PVD Subsystem Failure	Circuit board failure.	Recycle Power.
288	Diathermy Error	Circuit board failure.	Recycle Power.
290	PVD Subsystem Failure	Circuit board failure.	Recycle Power.
291	Phaco Handpiece Not Connected	Handpiece not connected or handpiece defective.	Check handpiece connection or replace handpiece. Retune.
292	Handpiece Not Tuned	Phaco mode was selected without tuning handpiece.	Tune handpiece and retry phaco. If tune unsuccessful, replace handpiece.
293, 295, 296, 297	PVD Subsystem Failure	Circuit board failure.	Recycle power.
302	IV Pole Not Ready	IV pole was moved without initialization.	1. Verify I/V pole connection. 2. Recycle power.
501	Prime Excessive Vacuum	Occlusion in line: improperly installed or defective tubing.	Check tubing for kinks, clogging and/or proper installation.
502	Prime Low Bottle Height	Occlusion in line: improperly installed or defective tubing.	Check tubing for kinks, clogging and/or proper installation.
503	Prime Low Vacuum	Occlusion in line: improperly installed or defective tubing.	Check tubing for kinks, clogging and/or proper installation.
505	Prime Vent Error	Occlusion in line: improperly installed or defective tubing.	Check tubing for kinks, clogging and/or proper installation.

Figure 10.2
Troubleshooting

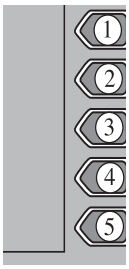
GENERAL	
Problem	**Corrective Action**
SOVEREIGN™COMPACT System does not come on when the power switch is turned on.	• Turn the power switch OFF. • Confirm that power cord is connected to console back panel. • Confirm that power cord is plugged into electrical receptacle or other power source. • Confirm that there is electrical power to the wall receptacle or power source. • If machine still does not come on, turn OFF. Check for blown fuses and replace if necessary (see page 10-16). • Contact AMO for Technical Service.
System comes on with wrong user interface language	• From the MAIN MENU, press softkey 4 (SYSTEM OPTIONS) • Press softkey 2 (LANGUAGES) • Highlight desired language • Press softkey 5 (SAVE) to select new language 
Foot pedal is not operating properly.	• Go to Diagnostics Foot Pedal Test on page 10-12. • Confirm the footpedal cord is connected at rear of console.
Programmable Power Pole does not respond.	• Pole may have reached maximum or minimum height. • Attempt Programmable Power Pole height adjustment via bezel or remote. • Confirm the IV pole cord is connected at rear of console.
Priming Errors	• Check tubing loading, including reloading manifold. • Reload pump segment; verify pump latch fully closed. • Verify no kinks, clogs, loose fittings. • Replace handpiece and tip - reprime. • Replace tubing set. • Check test chamber for proper installation and leaks.

Figure 10.2
Troubleshooting (Cont.)

IRRIGATION SYSTEM	
Problem	**Corrective Action**
No irrigation flow.	• Make sure I/A MODE is selected on front panel. • Check for kinks in the irrigation tubing. • Check tubing connection to handpiece. • Tap drip chamber to ensure valve is operating properly. • Check bottle height. • Press foot pedal to position 1 and check for flow. • Listen for the irrigation pinch valve in the tubing manifold area to confirm that it is operating when foot pedal is pressed. • If still no flow, replace tubing.
Reduced/insufficient irrigation flow. Irrigation flow continues even when foot pedal is Off (position 0).	• Verify roller clamp is open, if applicable. • Check for kinks in tubing, leaks in tubing or handpiece. • Check bottle height. • Check tubing connections. • Check for pinched irrigation sleeve at incision. • Check that foot pedal is unobstructed and not stuck in position 1. • Check foot pedal operation (see foot pedal test, p.10-11). • Verify that "continuous irrigation" is not active.
Anterior chamber too shallow or too deep.	• Check bottle height. • Too shallow, check for pinched irrigation sleeve at incision. • Check pump speed (flow rate). • Check that irrigation line is unobstructed.
Using large amounts of fluid.	• Check bottle height. • Check incision size. • Check flow rate (pump speed too high). • Check that no fluid is entering collection bag when not using irrigation. • Reseat or replace tubing.

Figure 10.2
Troubleshooting (Cont.)

ASPIRATION SYSTEM	
Problem	**Corrective Action**
No aspiration.	• Make sure appropriate MODE is selected on the front panel. • Check for kinks or clogs in tubing. • Check tubing connection to handpiece. • Ensure that handpiece is not clogged. • Press foot pedal to position 2 and check pump function.
Poor aspiration.	• Check flow rate. • Check foot pedal operation (see foot pedal test, page 10-11). • Check for kinks or clogs in tubing. • Ensure that handpiece is not clogged. • Check tubing connection to handpiece. • Check I/A handpiece o-rings for excessive wear. Replace o-rings, if needed.
Not building vacuum. Pump does not turn.	• Check programming. If the surgeon is in "linear vacuum" as opposed to "linear aspiration", the foot pedal must be depressed through position 2 for vacuum to read the pre-set maximum. • Be sure foot pedal is depressed. • Check tubing connection to handpiece. • Check for air in irrigation/aspiration tubing. • Check machine vacuum settings. • Replace tubing. • Run I/A prime. • Check vacuum preset. • Check flow rate.
Chamber shallowing or partially collapses.	• Check the bottle height and the handpieces for correct position. • Check flow rate setting. • Check tubing fittings to handpiece. • Check for kinks in tubing. • Remove handpiece and perform test chamber test to assure balance.

Figure 10.2
Troubleshooting (Cont.)

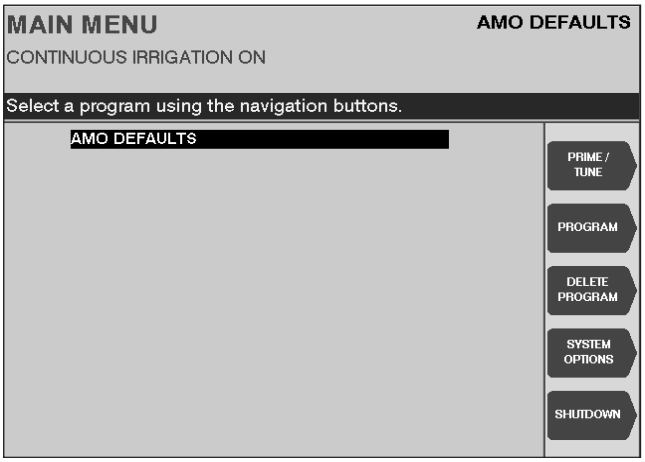
PHACOEMULSIFICATION SYSTEM	
Problem	**Corrective Action**
No phacoemulsification.	• Make sure that Phaco MODE is selected on the front panel. • Check foot pedal operation (see foot pedal test, page 10-11). • Make sure that phaco handpiece cord is properly connected to phaco receptacle on left side of machine. • Check the phaco power setting. • Ensure that phaco tip is tightened securely. • Check to make sure that the phaco tip is not damaged. • If damaged, replace with a new tip or replace the handpiece and reprime. • Verify that "irrigation only" is not active.
Poor or intermittent phacoemulsification.	• Check all of the corrective steps above for "No Phacoemulsification". • Remove phaco tip and retighten it. • Check phaco power delivery setting for both unoccluded and occluded (if applicable) settings. • Tune phaco handpiece.

DIATHERMY SYSTEM	
Problem	**Corrective Action**
No diathermy or poor diathermy.	• Make sure that Diathermy MODE is selected on the front panel. • Check foot pedal operation (see foot pedal test, page 10-11). • Check the diathermy power setting. • Check the diathermy cord for secure connection to the forceps and to the diathermy receptacles on the front panel. • Make sure that the diathermy cord connections are dry. • Re-attempt diathermy starting at a low power setting and gradually increase. • Verify that "irrigation only" is not active. • Replace the diathermy cord. • Replace the diathermy handpiece.
No sound when using diathermy.	• Make sure volume setting appears as 6 or greater in Settings. • Check for sounds when pushing any softkey or remote buttons. • Check for double ding upon completion of system start-up test (at power up). • Check for sound test (approx. 3 seconds) while running other self tests.

VITRECTOMY SYSTEM	
Problem	**Corrective Action**
No vitrectomy cutting or poor cutting.	• Make sure that the Vitrectomy MODE is selected on front panel. • Verify that surgeon is in foot pedal position 3, if IAC step vitrectomy is programmed. • Check the foot pedal operation (see foot pedal test, page 10-11). • Check tubing connections to vitrectomy handpiece. • Check vitrectomy tubing connection to the front (or side) panel receptacle. • Check the vitrectomy rate (CPM) setting on the front panel. Lower CPM, if necessary. • Check that irrigation and aspiration are working correctly. • Verify that cutter blade is stroking. • Replace vitrectomy cutter and try again.

Diagnostics

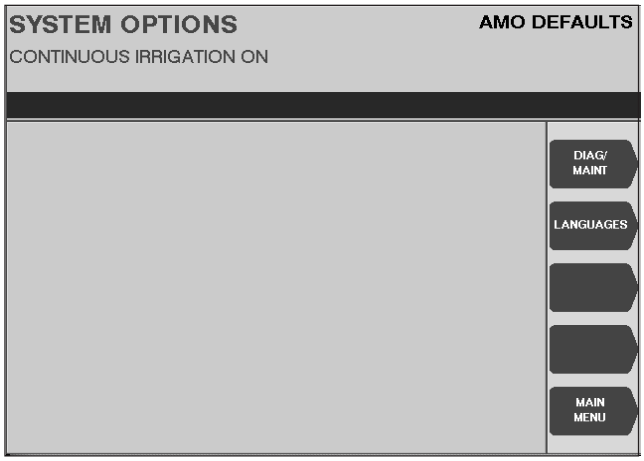
Diagnostics may be accessed via the Main Menu by selecting SYSTEM OPTIONS.



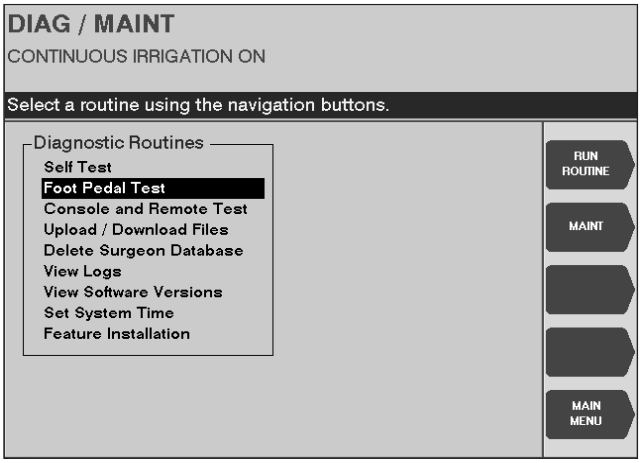
NOTE:

Maintenance Routines are special routines that are used by trained service personnel to perform system diagnostic and maintenance. Maintenance should only be performed by trained service personnel.

On the SYSTEM OPTIONS screen, select DIAG/MAINT.



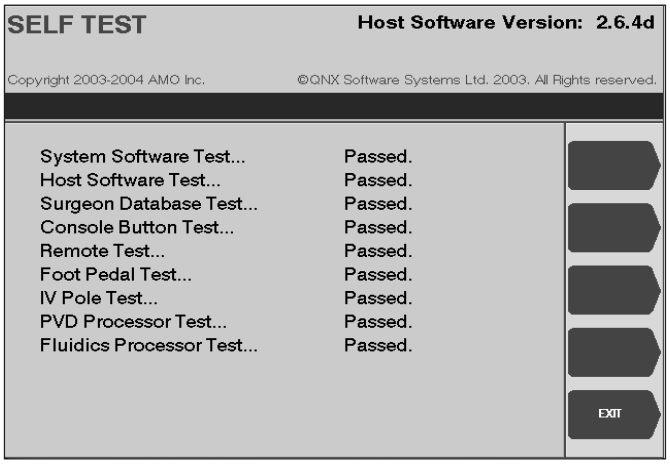
The DIAG/MAINT screen lists the various Diagnostic Routines. Using the navigation buttons or column select buttons, choose the desired routine and press RUN ROUTINE to execute the routine.



Diagnostics (Cont.)

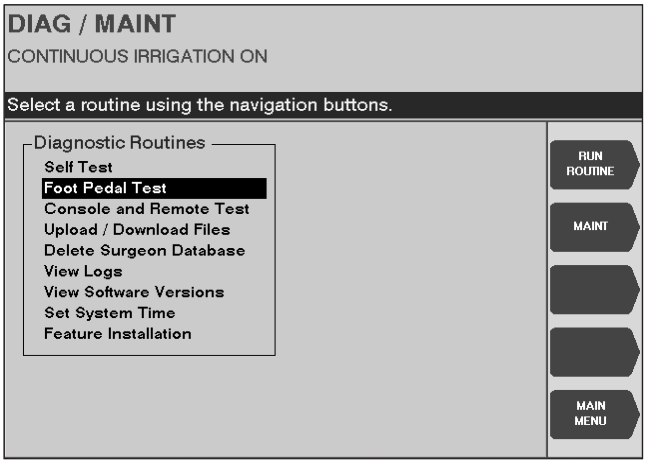
Self Test

The following Self Test screen is displayed as the routine is executed. Note that the current software version is displayed in the upper right of the screen. To discontinue the routine, Press EXIT.



Foot Pedal Test

The Foot Pedal Test is accessed via the DIAG/MAINT screen.

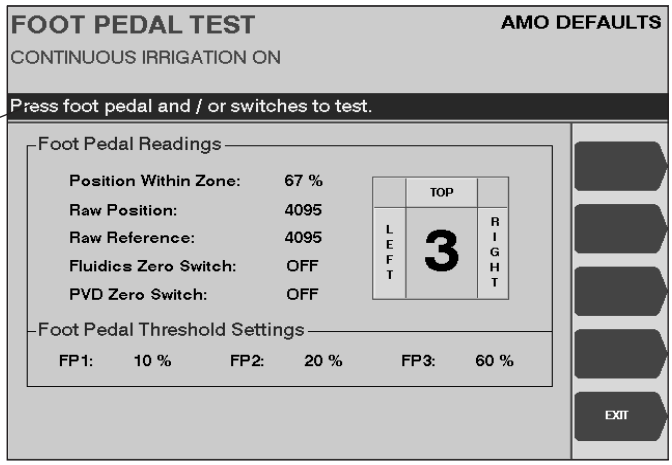


Diagnostics (Cont.)

Foot Pedal Test (Cont.)

Using the navigation buttons, select FOOT PEDAL TEST and press RUN ROUTINE. Follow the on-screen instructions to test the footpedal.

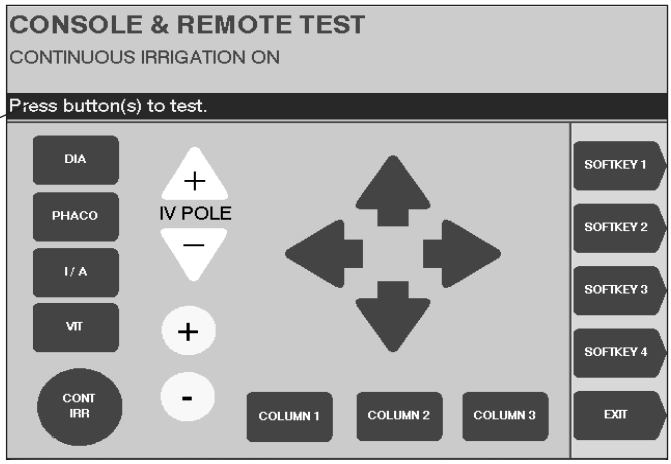
Follow instructions to perform test.



Console & Remote Test

The Console & Remote Test function provides a means for testing the buttons on both the console and the remote. When the buttons are pressed, the corresponding graphic symbol on the display will highlight to verify correct operation.

Follow instructions to perform test.



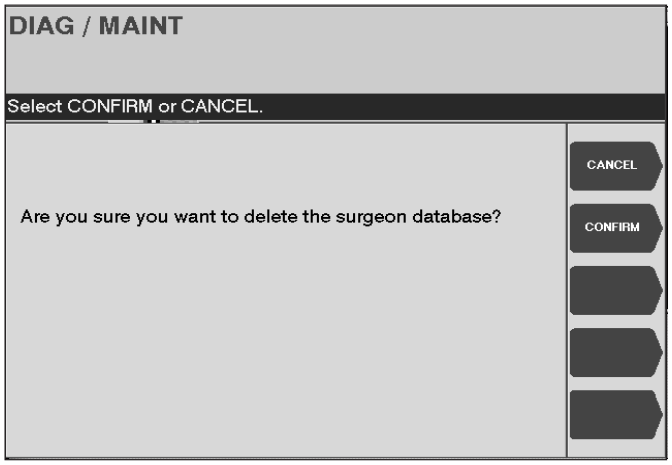
Upload/Download Files

The Upload/Download files routine enables file transfer from the machine to a separate storage medium and vice versa. This routine is available only to AMO authorized representatives.

Diagnostics (Cont.)

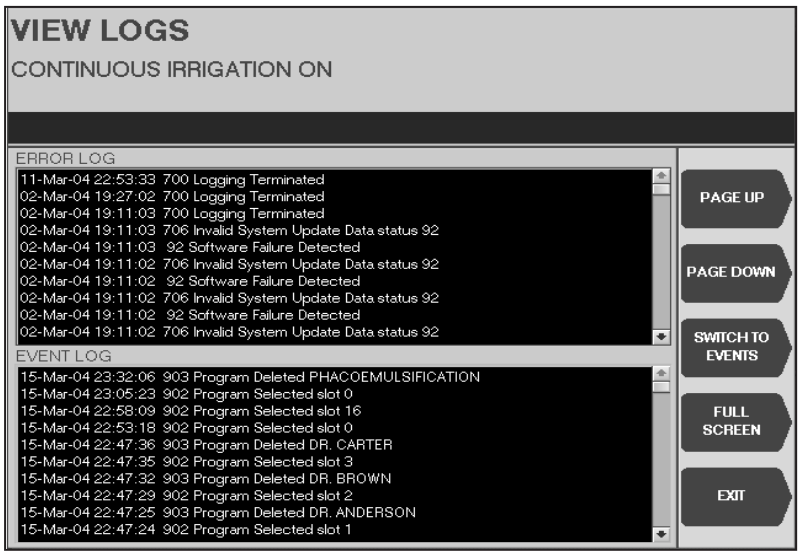
Delete Surgeon Database

The Delete Surgeon Database function allows you to delete all surgeon programs (except in the AMO Default program) in the SOVEREIGN™ COMPACT System memory. A confirmation screen appears to confirm the deletion before it is executed.



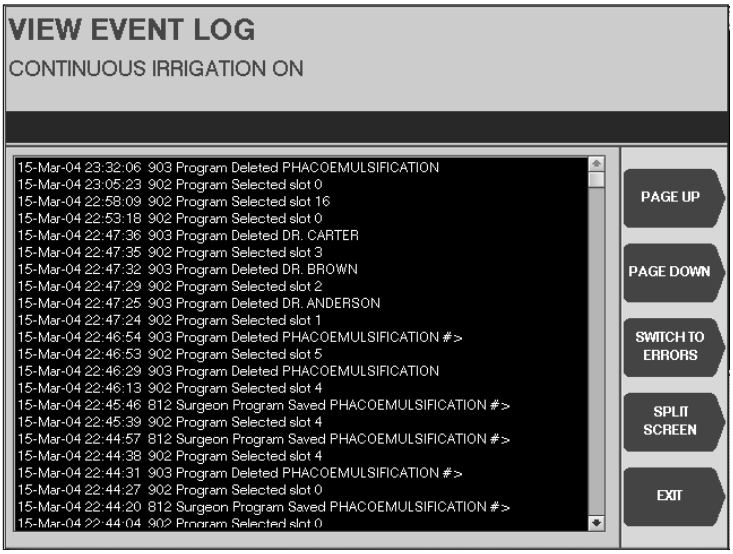
View Logs

The View Log function provides a summary, in reverse chronological order, of the Error Log and Event Log screens. The two logs may be viewed together on a split screen, or separately on a full screen. The soft keys provide the viewing and navigation functions.


VIEW LOGS
CONTINUOUS IRRIGATION ON
ERROR LOG
11-Mar-04 22:53:33 700 Logging Terminated
02-Mar-04 19:27:02 700 Logging Terminated
02-Mar-04 19:11:03 700 Logging Terminated
02-Mar-04 19:11:03 706 Invalid System Update Data status 92
02-Mar-04 19:11:03 92 Software Failure Detected
02-Mar-04 19:11:02 706 Invalid System Update Data status 92
02-Mar-04 19:11:02 92 Software Failure Detected
02-Mar-04 19:11:02 706 Invalid System Update Data status 92
02-Mar-04 19:11:02 92 Software Failure Detected
02-Mar-04 19:11:02 706 Invalid System Update Data status 92
EVENT LOG
15-Mar-04 23:32:06 903 Program Deleted PHACOEMULSIFICATION
15-Mar-04 23:05:23 902 Program Selected slot 0
15-Mar-04 22:58:09 902 Program Selected slot 16
15-Mar-04 22:53:18 902 Program Selected slot 0
15-Mar-04 22:47:36 903 Program Deleted DR. CARTER
15-Mar-04 22:47:35 902 Program Selected slot 3
15-Mar-04 22:47:32 903 Program Deleted DR. BROWN
15-Mar-04 22:47:29 902 Program Selected slot 2
15-Mar-04 22:47:25 903 Program Deleted DR. ANDERSON
15-Mar-04 22:47:24 902 Program Selected slot 1
PAGE UP
PAGE DOWN
SWITCH TO EVENTS
FULL SCREEN
EXIT

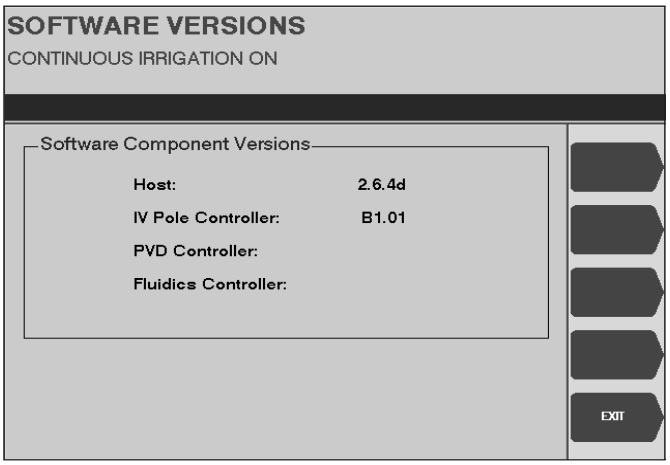
Diagnostics (Cont.)

View Logs (Cont.)


VIEW EVENT LOG
CONTINUOUS IRRIGATION ON
15-Mar-04 23:32:06 903 Program Deleted PHACOEMULSIFICATION
15-Mar-04 23:05:23 902 Program Selected slot 0
15-Mar-04 22:58:09 902 Program Selected slot 16
15-Mar-04 22:53:18 902 Program Selected slot 0
15-Mar-04 22:47:36 903 Program Deleted DR. CARTER
15-Mar-04 22:47:35 902 Program Selected slot 3
15-Mar-04 22:47:32 903 Program Deleted DR. BROWN
15-Mar-04 22:47:29 902 Program Selected slot 2
15-Mar-04 22:47:25 903 Program Deleted DR. ANDERSON
15-Mar-04 22:47:24 902 Program Selected slot 1
15-Mar-04 22:46:54 903 Program Deleted PHACOEMULSIFICATION #>
15-Mar-04 22:46:53 902 Program Selected slot 5
15-Mar-04 22:46:29 903 Program Deleted PHACOEMULSIFICATION
15-Mar-04 22:46:13 902 Program Selected slot 4
15-Mar-04 22:45:46 812 Surgeon Program Saved PHACOEMULSIFICATION #>
15-Mar-04 22:45:39 902 Program Selected slot 4
15-Mar-04 22:44:57 812 Surgeon Program Saved PHACOEMULSIFICATION #>
15-Mar-04 22:44:38 902 Program Selected slot 4
15-Mar-04 22:44:31 903 Program Deleted PHACOEMULSIFICATION #>
15-Mar-04 22:44:27 902 Program Selected slot 0
15-Mar-04 22:44:20 812 Surgeon Program Saved PHACOEMULSIFICATION #>
15-Mar-04 22:44:04 902 Program Selected slot 0
PAGE UP
PAGE DOWN
SWITCH TO ERRORS
SPLIT SCREEN
EXIT

View Software Versions

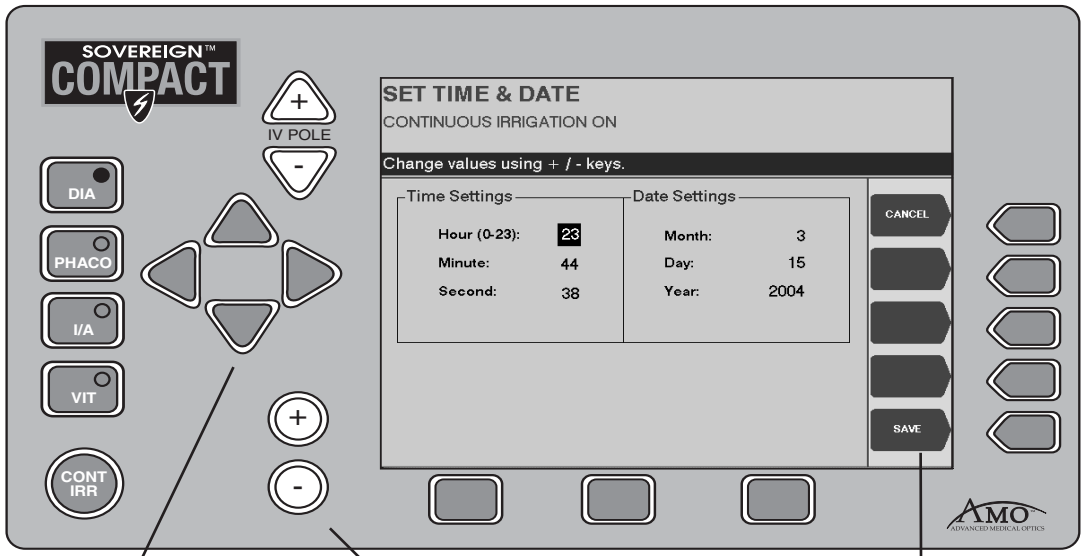
This function is for information only, and displays all current software versions used on the SOVEREIGN™ COMPACT system.



Diagnostics (Cont.)

The system time and date may be adjusted using the Set Time & Date function. To adjust the time, follow the instructions below.

Set System Time



Use Navigation buttons to select time/date to be changed.

Use Value Adjust buttons to set the correct time/date values.

Press to save new time/date in system memory.

Fuse Replacement Procedure

If the SOVEREIGN™ COMPACT System does not switch on when the power switch is turned ON, and you have confirmed that the power cord is properly connected and plugged in, it may be possible that a fuse has blown. To prevent the risk of fire or damage to the instrument, replace the fuses with the exact type and rating as indicated below (check the voltage sticker on the back panel of the SOVEREIGN™ COMPACT System to confirm your machine voltage):

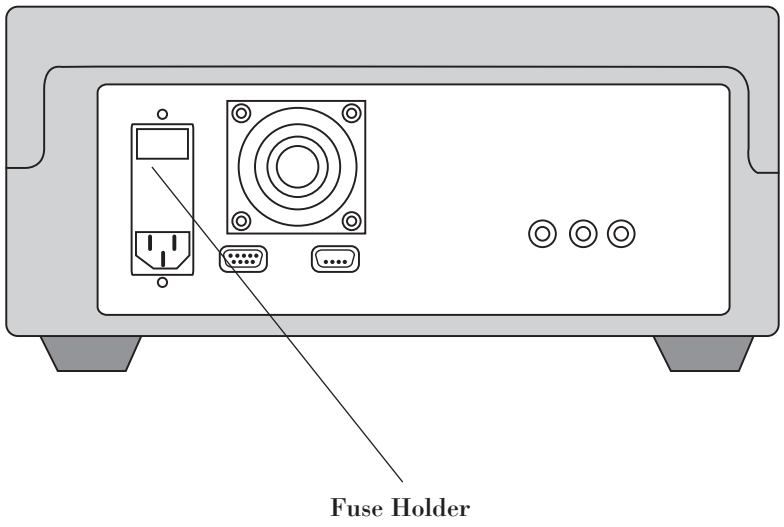
Figure 10.3
Fuse Specifications

	Voltage	Quantity	Fuse Specifications
Console	100/120/240	2	6.3A, 250V, Bussman GDA 6.3 (or equivalent)

To replace the console fuses:

1. Unplug the SOVEREIGN™ COMPACT System from electrical power and the power cord from the back panel.
2. Locate the fuse holder on the back panel of the SOVEREIGN™ COMPACT System, as shown in Figure 10.4.

Figure 10.4
Back Panel Fuse Holder



Fuse Replacement Procedure (Cont.)

3. Using a small screwdriver, gently pry open the cover to expose the fuse holder.
4. Gently pry out the fuse holder.
5. Pop out the bad fuse(s) and replace it (them) with new fuse(s) (value and size specified above).
6. Replace the fuse holder, making sure that the arrows are pointing to the right of the back panel. Tilt the fuse holder slightly to the right and push in.
7. Push the fuse holder cover up and in until it snaps closed.
8. Reconnect power cord to back panel and plug into wall receptacle.

11 U.S. WARRANTY AND MAINTENANCE*

Warranty Statement

AMO warrants for a period of two years (24 months) from the date of installation of the SOVEREIGN™ COMPACT System console, foot pedal, remote control, Programmable Power Pole and the Phacoemulsification Ultrasonic Handpiece to be free from defects in materials and workmanship when properly installed, maintained, and used for its intended purpose. **MISUSE AND MISHANDLING ARE NOT COVERED UNDER WARRANTY.** AMO's sole obligation shall be to repair or replace, at its option, the defective part(s).

The Irrigation/Aspiration Handpiece Set, Diathermy Forceps and Diathermy Cord are warranted for ninety (90) days. The TAC handpiece is warranted for one (1) year.

This warranty applies only to the original purchaser/user of the device and only so long as the equipment is used in the country to which it was originally shipped by AMO.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL AMO BE LIABLE TO THE PURCHASER FOR CONSEQUENTIAL DAMAGES.

Extended Warranty

Extended Warranty Contracts (excluding the Phacoemulsification Ultrasonic Handpiece) may be available. Contact AMO for information on the availability of an Extended Warranty Contract.

* If outside the United States, please contact your local AMO office or representative for warranty information.

Maintenance

User maintenance of the SOVEREIGN™ COMPACT System is limited to those adjustments and corrective actions given in Section 10, Error Messages, Troubleshooting and Diagnostics. There are no user serviceable components within the machine and you should not attempt to access the internal components. Any attempt to do so may void the warranty.

Routine or periodic maintenance of the SOVEREIGN™ COMPACT System by an AMO representative is recommended at least annually. AMO recommends the measurement of PE resistance and leakage current according to IEC 601-1 every two years.

If a problem persists following setup, check-out and troubleshooting as per the procedures given in this manual, contact AMO for corrective action (1-800-449-3060 in USA). Please contact your local AMO office or representative for region specific phone numbers.

12 SPECIFICATIONS

Physical Specifications

		English / U.S.	Metric:
SOVEREIGN™ COMPACT Console System:			
Console Dimensions (with display)	Width	14 inches	36 cm
	Depth	18 inches	46 cm
	Height	7.5 inches	19 cm
Weight		31 pounds	14 kg
Power Cord Length		10 feet	305 cm
Electrical Enclosure Current Leakage		IEC 601-1 compliance	
Cart:	Width	15 inches	38 cm
	Depth	22 inches	56 cm
	Height	42 inches	107 cm
Wheel Base	Width	25 inches	64 mm
	Depth	24 inches	61 mm
Weight		66 pounds	30 kg
Foot Pedal:			
Dimensions	Width	6 inches	15 cm
	Depth	10 inches	25 cm
	Height	5 inches	13 cm
Weight		9 pounds	4 kg
Cord Length		11.8 feet	360 cm
Power IV Pole:			
Max. Power IV Pole Travel		34 inches	80 cm
Settings Range		0-32 inches	0-80 cm
Velocity		2.4 inches/sec	6 cm/sec.
Maximum Lift Weight		10 pounds	4.5 kg

Electrical Specifications

	Voltage	Frequency	Power Consumption	Fuse Rating	Enclosure Current Leakage
System	100/120/240 Vac	50/60 Hz	225 VA	6.3A, 250V, Bussman GDA 6.3 (or equivalent)	<100 uA

Environmental Specifications	Operating Temperature Humidity	10 to 40˚C 0 to 95% RH, non-condensing
Storage Conditions	Storage Temperature Humidity	-20 to 60˚C 0 to 95% RH, non-condensing
Diathermy Specifications	Power Adjustment Diathermy Power (maximum power into rated load) Diathermy Type	5 to 100%, in 5% increments 10 Watts into 100 ohms 386 KHz Bipolar

Figure 12.1
Diathermy Power Graph (10 ohm rated load)

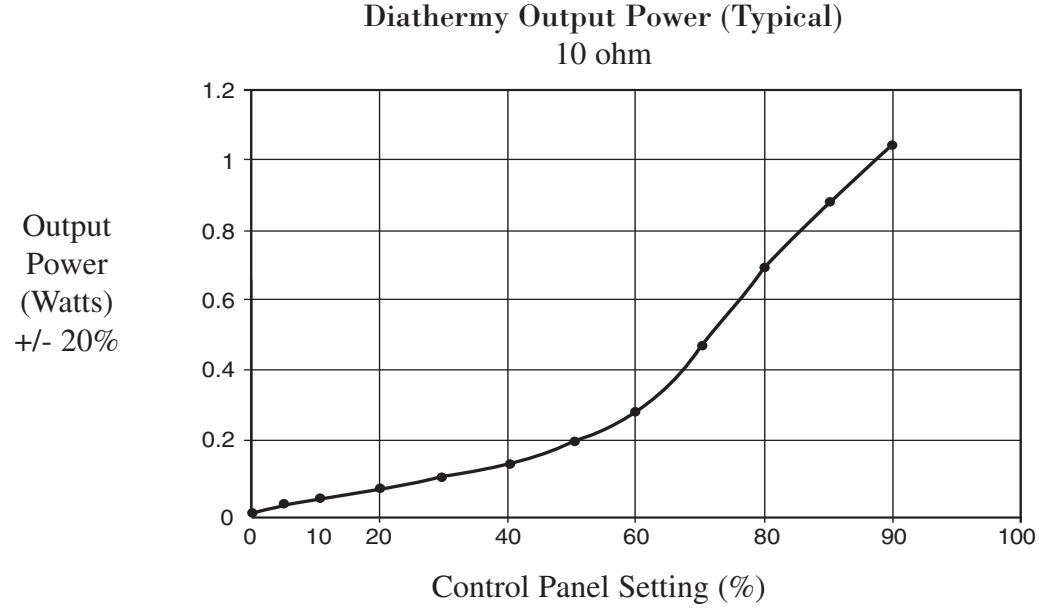


Figure 12.2
Diathermy Power Graph (50 ohm rated load)

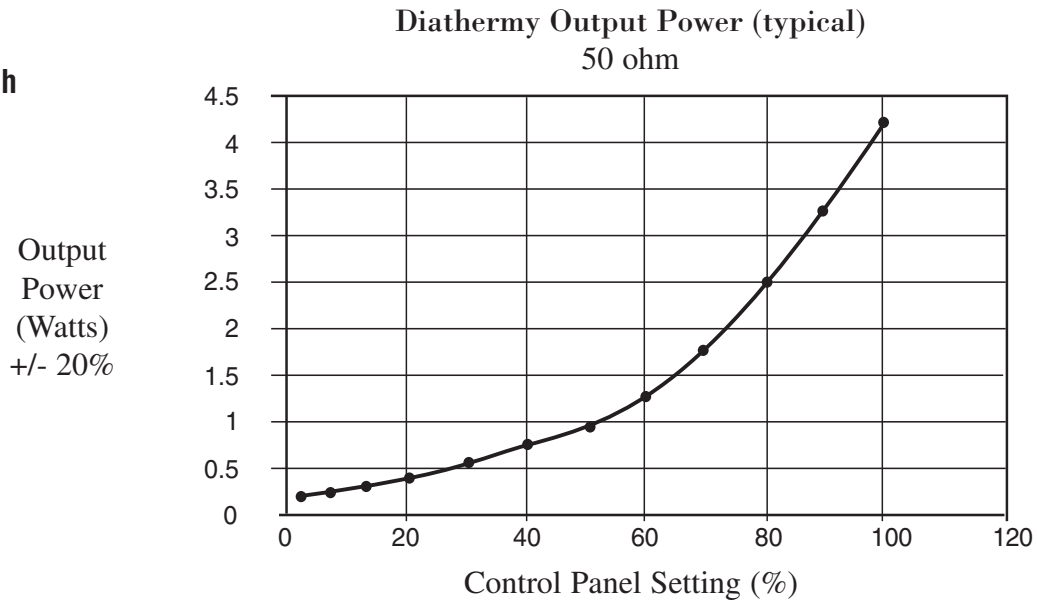


Figure 12.3
Diathermy Power Graph (100 ohm rated load)

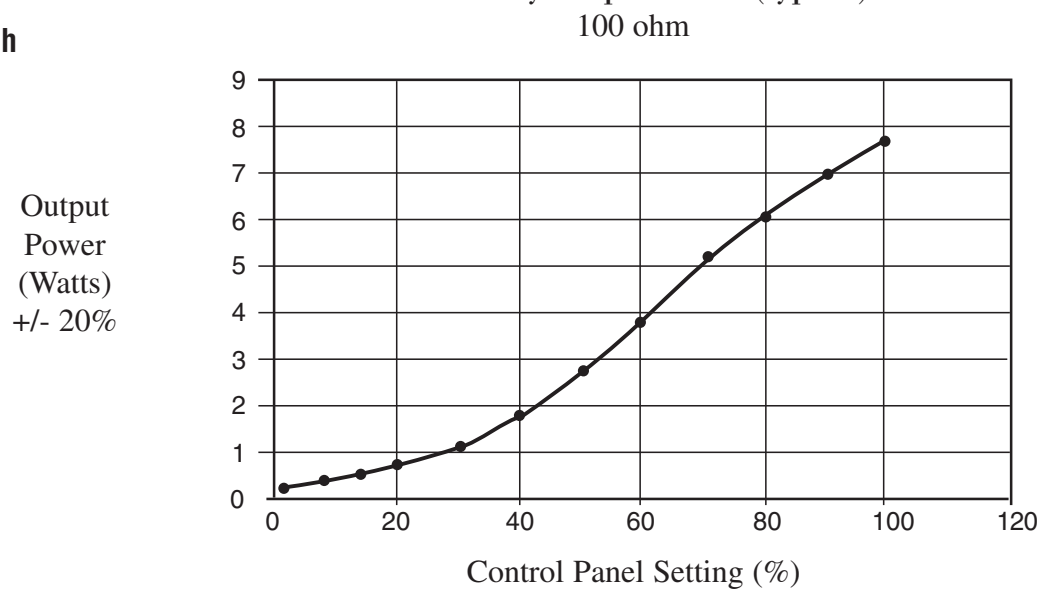


Figure 12.4
Diathermy Power Graph (200 ohm rated load)

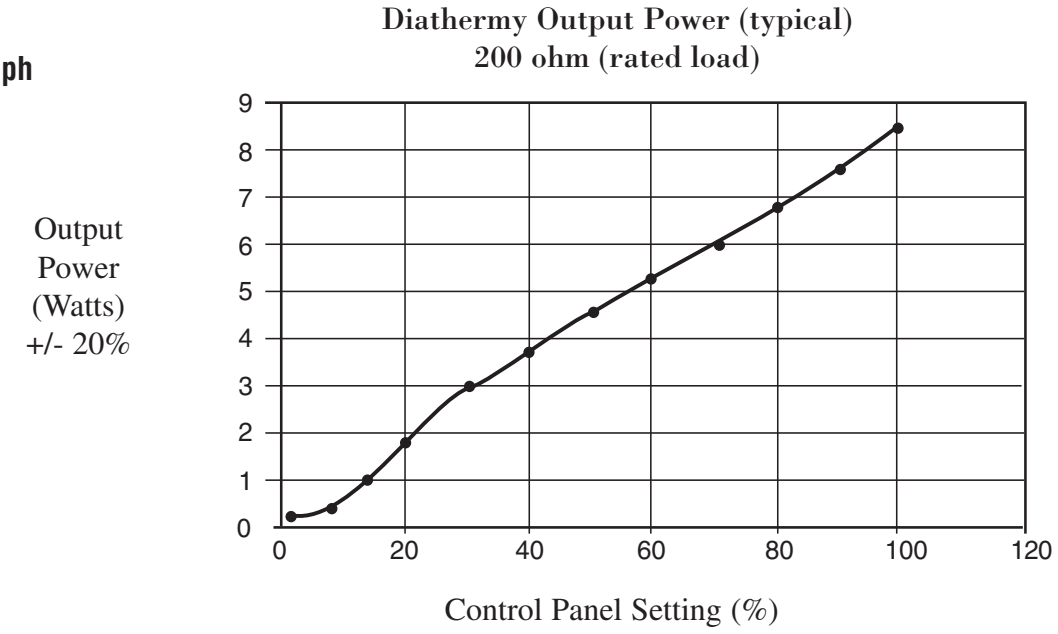


Figure 12.5
Diathermy Power Graph (500 ohm rated load)

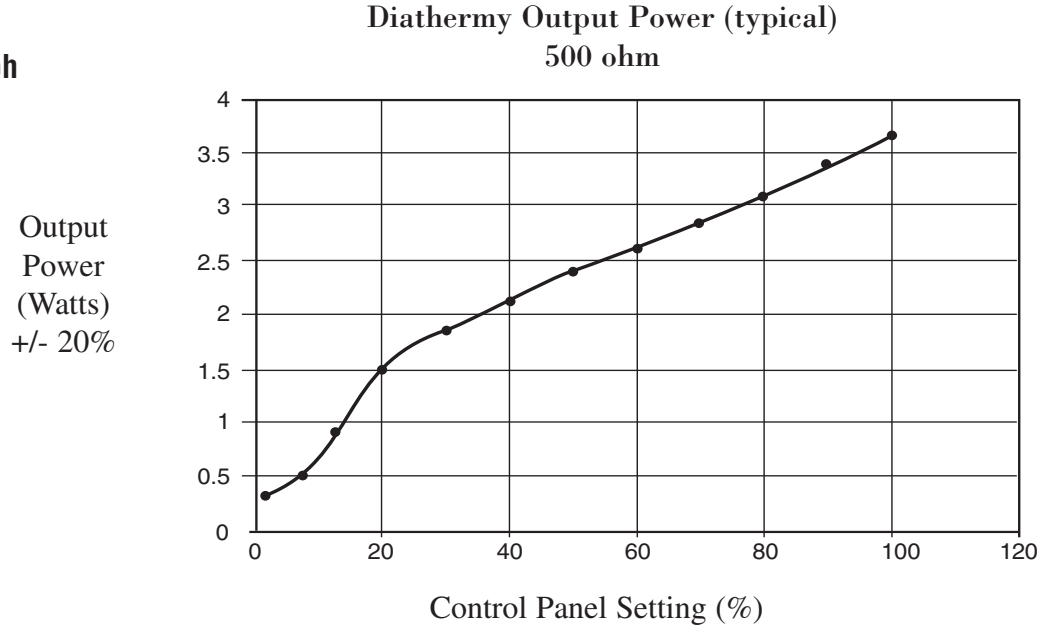


Figure 12.6
Diathermy Power Graph (1000 ohm rated load)

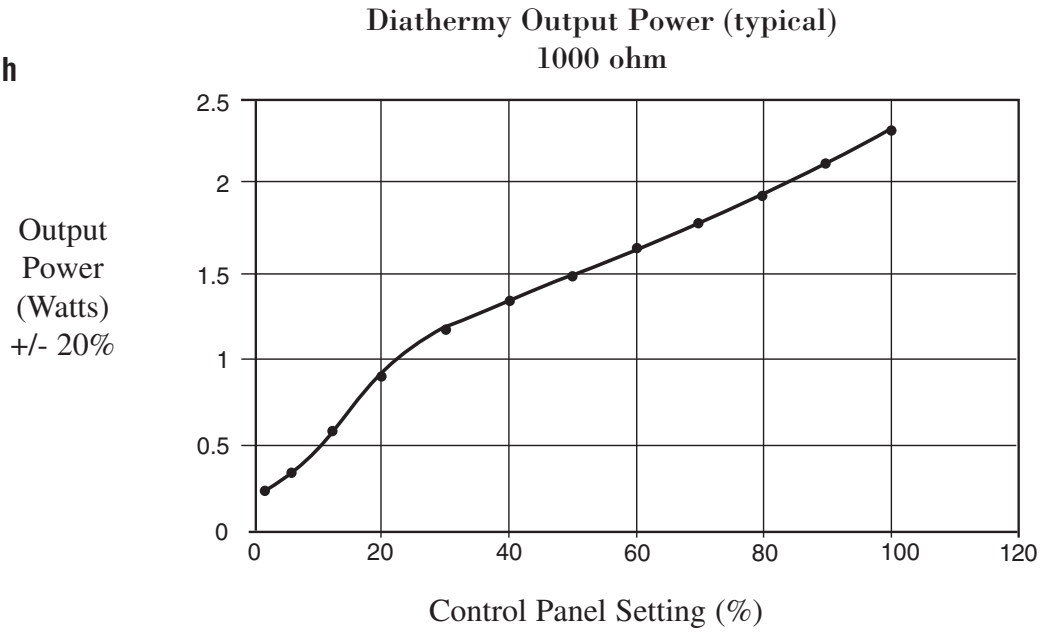


Figure 12.7
Diathermy Power VS. Load Impedance (100% power)

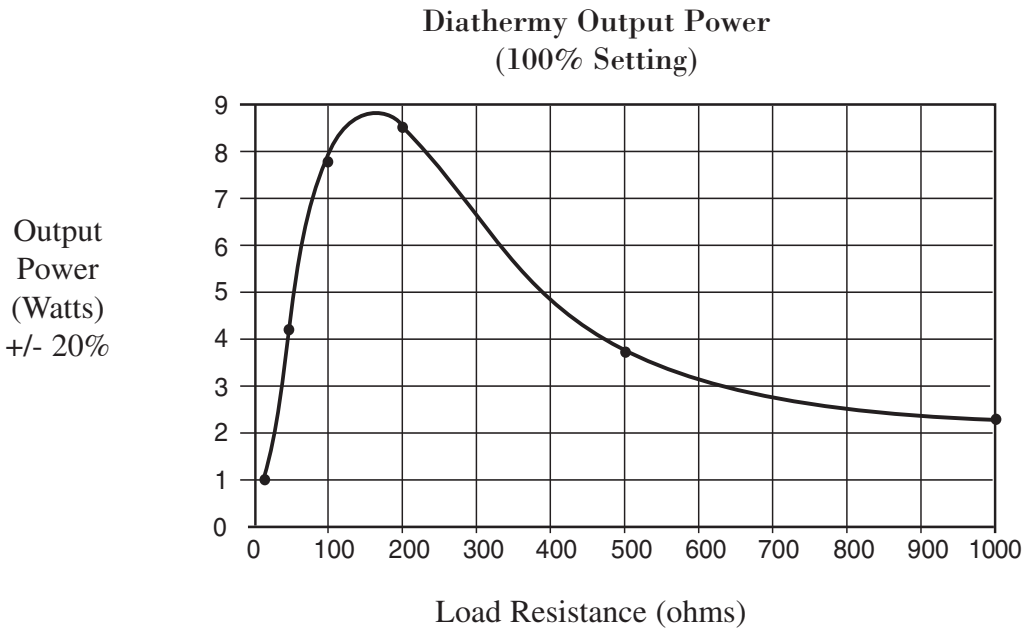
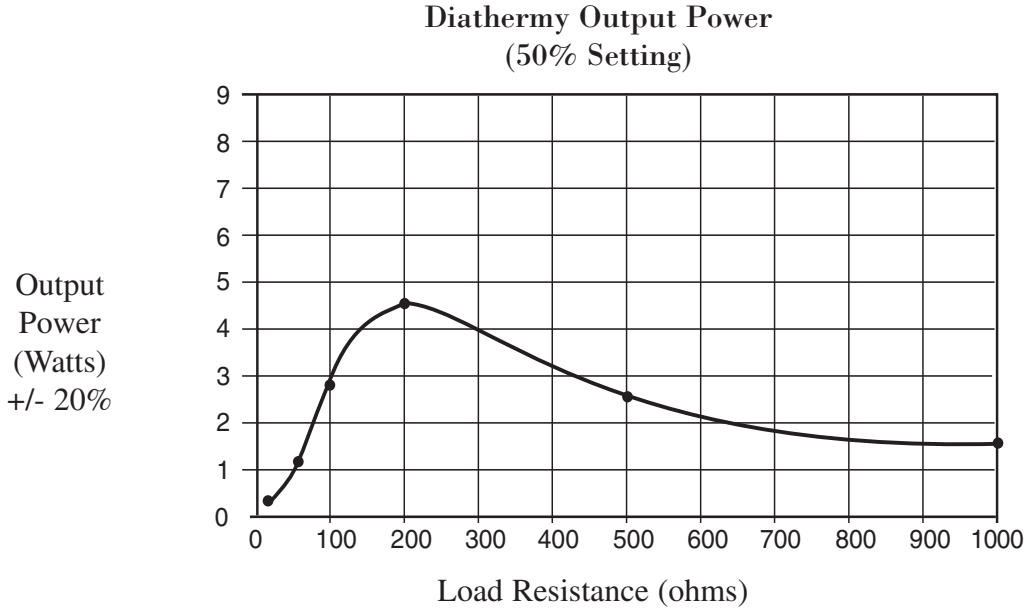


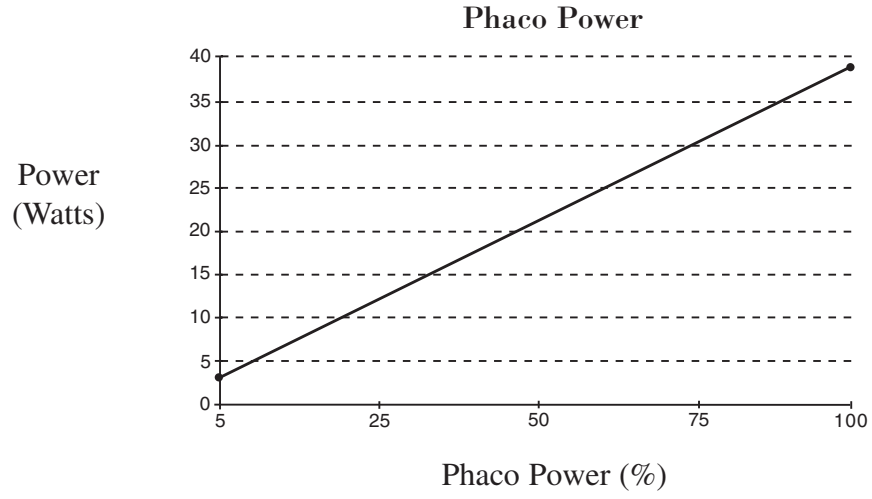
Figure 12.8
Diathermy Power VS. Load Impedance (50% power)



I/A Specifications	Vacuum Level	0 to 500 mmHg
	Pump Flow	0 to 50 cc/minute

Phaco Specifications	Phaco Power	0 to 100%, in 5% increments
	Phaco Vacuum Levels	0-500 mmHg in 5 mmHg increments
	Pump Flow Rate	10 to 50 cc/minute, in 2 cc increments

Figure 12.9
Phaco Power Graph



Vitrectomy Specifications	Electric Oscillating (EVIT) Cutter Rate	100 to 600 cuts per minute (CPM)

13 ACCESSORIES AND PARTS REORDERING

In this section you will find:

- List of Accessories with Part Numbers

Parts Reordering

Following is a list of accessories that you may periodically need to reorder for your SOVEREIGN™ COMPACT. Your AMO representative can advise you of recommended inventory levels based on the volume of phacoemulsification procedures done in your facility. All of the items listed below may be ordered through your AMO representative or directly through AMO Customer Service.

System Component	Description	Part No.
Phaco Handpiece	AMO Phaco Handpiece	SOV680290
	19 Gauge LAMINAR™ Flow Phaco Tip, 0˚ Round Tip	OPOR0019L
	19 Gauge LAMINAR™ Flow Phaco Tip, 15˚ Round Tip	OPOR1519L
	19 Gauge LAMINAR™ Flow Phaco Tip, 30˚ Round Tip	OPOR3019L
	19 Gauge LAMINAR™ Flow Phaco Tip, 45˚ Round Tip	OPOR4519L
	Disposable 20 Gauge LAMINAR™ Flow Phaco Tip, 0˚ Round Tip	OPOD0020L
	Disposable 20 Gauge LAMINAR™ Flow Phaco Tip, 15˚ Round Tip	OPOD1520L
	Disposable 20 Gauge LAMINAR™ Flow Phaco Tip, 30˚ Round Tip	OPOD3020L
	Disposable 20 Gauge LAMINAR™ Flow Phaco Tip, 45˚ Round Tip	OPOD4520L
	Disposable LAMINAR™ Flow Phaco Tip, 19 Gauge, 30˚ Curved	OPOCR3019L
	Disposable LAMINAR™ Flow Phaco Tip, 20 Gauge, 30˚ Curved	OPOCR3020L
	19 Gauge LAMINAR™ Flow Irrigation Sleeve and Test Chamber	OPOS19L
	Disposable 20 Gauge LAMINAR™ Flow Infusion Sleeve and Test Chamber	OPOD20L
	LAMINAR™ Flow Tip Wrench	OPOMTWL
	SOLO™ I/A Handpiece, 20 Ga., Curved Silicone Sleeve Tip	OPOIA20CRV
	SOLO™ I/A Handpiece, 20 Ga., 45˚ Silicone Sleeve Tip	OPOIA2045D
	SOLO™ I/A Handpiece, 20 Ga., Straight Silicone Sleeve Tip	OPOIA20STR
	SOLO™ I/A Handpiece Kit	OPOIA20KIT
	Cleaning/Flushing Kit	OM05510114
	Sterilization Tray	MSR309
Diathermy Handpiece	Power Cable	K106075
	Forcep	K121085
	Oscillating TAC Vitrectomy Handpiece	OM0201011D
	Oscillating TAC Infusion Sleeve (1.65 mm)	OM0527011
	23 Gauge Limbal Infusion Cannula	OM0504011
Tubing Packs	Tubing Pack (disposable, sterile)	OPO60
	Tubing Pack (reusable, sterile)	OPO65
	Administration Set	OM2505191
	Drain Bag	OPO56
Remote Control	SOVEREIGN™ COMPACT System Remote Control	CMP680135
Foot Pedal	SOVEREIGN™ COMPACT System Foot Pedal	CMP680700
	SOVEREIGN™ COMPACT System Open-Toe Foot Pedal	CMP680720
Cart	SOVEREIGN™ COMPACT Cart	CMP680002
	SOVEREIGN™ COMPACT IV Pole	CMP680P2
	Arm and Tray Cover Sterile	OM271000
	Phaco Sterilization Tray (1 1/4" deep)	OM2908011
	TAC Sterilization Tray (3/4" deep)	OM2908012
	Mayo Tray	OM290901

System Component	Description	Part No.
Miscellaneous	SOVEREIGN™ COMPACT System Owner's Manual	CMPZ370049
	SOVEREIGN™ COMPACT System Owner's Manual-Multilingual CE	CMPZ370054
	100/120V Power Cord with Hospital Plug	SOV201301C
	Euro Power Cord	4000-802
	SOVEREIGN™ COMPACT Carrying Case	CMP680900
	SOVEREIGN™ COMPACT IV Pole Carrying Case	CMP680901
	SOVEREIGN™ COMPACT Cart Carrying Case	CMP680902

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